CPMG / KA / BG-GPO/13/2003-2005



ಕರ್ನಾಟಕ ರಾಜ್ಯಪತ್ರ

ಅಧಿಕೃತವಾಗಿ ಪ್ರಕಟಿಸಲಾದುದು

ಸಂಪುಟ ೧೪೦	ಬೆಂಗಳೂರು, ಗುರುವಾರ, ಜೂನ್ ೯, ೨೦೦೫ (ಜ್ಯೇಷ್ಠ ೧೯, ಶಕವರ್ಷ ೧೯೨೭)	ಸಂಚಿಕೆ ೨೩

ಭಾಗ - ೪

ಕೇಂದ್ರದ ವಿಧೇಯಕಗಳು ಮತ್ತು ಅವುಗಳ ಮೇಲೆ ಪರಿಶೀಲನಾ ಸಮಿತಿಯ ವರದಿಗಳು, ಕೇಂದ್ರದ ಅಧಿನಿಯಮಗಳು ಮತ್ತು ಅಧ್ಯಾದೇಶಗಳು, ಕೇಂದ್ರ ಸರ್ಕಾರದವರು ಹೊರಡಿಸಿದ ಸಾಮಾನ್ಯ ಶಾಸನಬದ್ಧ ನಿಯಮಗಳು ಮತ್ತು ಶಾಸನಬದ್ಧ ಆದೇಶಗಳು ಮತ್ತು ರಾಷ್ಟ್ರಪತಿಯವರಿಂದ ರಚಿತವಾಗಿ ರಾಜ್ಯ ಸರ್ಕಾರದವರಿಂದ ಪುನಃ ಪ್ರಕಟವಾದ ಆದೇಶಗಳು.

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 88 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 31ನೇ ಮಾರ್ಚ್, 2005

2005ನೇ ಸಾಲಿನ ಫೆಬ್ರವರಿ 3ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.151 (Notification No. F.No.17011/18/96-1A-III) ದಿನಾಂಕ:03.02.2005ನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

ORDER

S.O. 151(E): Whereas, by an Order of the Government of India in the Ministry of Environment and Forests S.O. number 21 (E) Dated the 4th January, 2002, the Central Government constituted the Karnataka State Coastal Zone Management Authority, for a period of three years and the term of the said Authority has expired;

And, whereas, the Central Government is of the view that such an Authority must be reconstituted;

Now, therefore, in exercise of powers conferred by sub-sections (1) and (3) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986) (hereinafter referred to as the said Act), the Central Government hereby reconstitutes the Karnataka State Coastal Zone Management Authority (hereinafter referred to as the Authority) with effect from the date of publication of this Order in the official Gazette, for a period upto 31st March, 2005 consisting of the following persons, namely:

1.	Principal Secretary, Department of Environment and Forests, Government of Karnataka.	Chairman
2.	Director, Department of Industries, Government of Karnataka.	Member
3.	Chairman, Karnataka State Pollution Control Board, Government of Karnataka.	Member
4.	Sh. Pranabes Sanyal Chief Conservator of Forests, Government of West Bengal, Kolkata.	Member

5.	Dr. H. Honne Gowda, Director, Karnataka Remote Sensing Unit, Bangalore.	Member
6.	Chief Conservator of Forests, Regional Office, Ministry of Environment and Forests, Kendriya sadan, Koramangala, Bangalore.	Member
7.	Director, Environment Technical Cell, Department of Forests, Ecology and Environment, Government of Karnataka.	Member-Secretary

II. The Authority shall have the power to take the following measures for protecting and improving the quality of the coastal environment and preventing, abating and controlling environmental pollution in the coastal areas of the State of Karnataka, namely:

(i) Examination of proposals for changes or modifications in classification of Coastal Regulation Zone areas and in the Coastal Zone Management Plan (CN;/IP) received from the Karnataka State Government and making specific recommendations to the National Coastal Zone Management Authority therefore.

(ii) (a) Inquire into cases of alleged violations of the provisions of the said Act or the rules made thereunder, or under any other law which is related to the objects of the said Act and, if found necessary in a specific case, issuing directions under section 5 of the said Act, insofar as such directions are not inconsistent with any direction issued in that specific case by the National Coastal Zone Management Authority or by the Central Government;

(b) Review of cases involving violations of the provisions of the said Act, and the rules made thereunder, or under any other law which is related to the objects of the said Acts, and if found necessary referring such cases, with comments, for review to the National Coastal Zone Management Authority:

Provided that the cases under sub-clauses (a) and (b) of this sub-paragraph may either be taken up suo-moto or on the basis of complaint made by an individual or a representative body or an organization.

(iii) Filing complaints under section 19 of the said Act in cases of non-compliance of the directions issued by it under sub-clause (a) of sub-paragraph (ii) of paragraph II of the Order.

(iv) To take action under section 10 of the said Act to verify the facts concerning the issues arising from sub-paragraphs (i) and (ii) of paragraph II of this Order.

III. The Authority shall deal with environmental issues relating to Coastal Regulation Zone, which may be referred to it by the Karnataka State Government, the National Coastal Zone Management Authority or the Central Government.

IV. The Authority shall identify ecologically sensitive areas in the Coastal Regulation Zone and formulate area-specific management plans for such identified areas.

V. The Authority shall identify coastal areas highly vulnerable to erosion or degradation and formulate area specific management plans for such identified areas.

VI. The Authority shall identify economically important stretches in Coastal regulation Zone and prepare Integrated Coastal Zone Management Plans for the same.

VII. The Authority shall submit the plans prepared by it under paragraphs IV, V and VI above and modifications thereof to the National Coastal Zone Management Authority for examination and its approval.

VIII. The Authority shall examine all projects proposed in Coastal Regulation Zone areas and give their recommendations before the project proposals are referred to the Central Government or the agencies who have been entrusted to clear such projects under the notification, of the Government of India in the Ministry of Environment and Forests vide number S.O. 144 (E) dated 19th February, 1991.

IX. The Authority shall ensure compliance of all specific conditions that are stipulated and laid down in the approved Coastal Zone Management Plan of Karnataka.

X. The Authority shall ensure that atleast two third members of the Authority are present during the meetings.

XI. The Authority shall furnish report of its activities at least once in six months to the National Coastal Zone Management Authority.
XII. The foregoing powers and functions of the Authority shall be subject to the supervision and control of the Central Government.
XIII. The Authority shall have its headquarters at Bangalore.
XIV. The Authority shall open an account in any of the nationalized banks in the name of the Authority for the purpose of receiving funds provided for undertaking the activities and functions listed in this order.
XV. Any matter specifically not falling within the scope and jurisdiction of the Authority so constituted shall be dealt with by the statutory authorities concerned.

[F.No. 17011/18/96-IA-III]
R. CHANDRAMOHAN, Jt. Secy.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,
ರಿಚಾರ್ಡ್ ಲೋಬೋ
ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ
ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,
ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 96

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 93 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 31ನೇ ಮಾರ್ಚ್, 2005

2005ನೇ ಸಾಲಿನ ಫೆಬ್ರವರಿ 9ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.182 (E) (Notification No. F.No.2/1/2003-Plant (B) ದಿನಾಂಕ:09.02.2005ನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF COMMERCE AND INDUSTRY
(Department of Commerce)
(COFFEE CONTROL)
NOTIFICATION
New Delhi, the 9th February, 2005

S.O. 182(E): Whereas the Central Government, in exercise of the powers conferred by Sub-section (2) of Section 4 of the Coffee act, 1942 (7 of 1942), read with rule 3 and sub-rule (1) of rule 4 of the Coffee Rules, 1955, appointed certain members of the Coffee Board vide notification number S.O. 463(E), dated the 23rd April, 2003;

And, whereas two casual vacancies have arisen in the Coffee Board as Shri D.C. Srikantappa and Smt. D.M. Vijayakumari ceased to be members of Lok Sabha with dissolution of XIIIth Lock Sabha and the Lok Sabha has elected Shri D.V. Sadananda Gowda and Shri K.C. Palanisamy, Members of Parliament for appointment as members of the Coffee Board in place of Shri D.C. Srikantappa and Smt. D.M. Vijayakumari respectively;

Now, therefore, in exercise of the powers conferred by clause (b) of Sub-section (2) of Section 4 of the Coffee Act, 1947 (7 of 1947), read with rule 3 and sub-rules (1) and (2) of rule 4 of the Coffee Rules, 1955, the Central Government hereby appoints Shri D.V. Sadananda Gowda and Shri K.C. Palanisamy, members of Lok Sabha as members of the Coffee Board with effect from the date of publication of this notification and for that purpose makes the following further amendment in the notification of the Government of India in the Ministry of Commerce and Industry, Department of Commerce, number S.O. 463(E), dated the 23rd April, namely:

In the said notification, for serial numbers 1 and 2 and the entries relating thereto, the following serial numbers and entries shall be substituted, namely:

"1.	Shri D.V. Sadananda Gowda, Member of Parliament (Lok Sabha)	He shall hold office up to 22.04.2006 or till he ceases to be a member of the House whichever is earlier.
2.	Shri K.C. Palanisamy, Member of Parliament (Lok Sabha)	He shall hold office up to 22.04.2006 or till he ceases to be a member of the House whichever is earlier."

[F.No.2/1/2003-Plant (B)]
A. SENGUPTA, Addl. Secy.

Foot Note: The principal notification was published in the Gazette of India, Extraordinary, vide number S.O.463(E), dated the 23rd April, 2003 and was amended vide notifications number S.O. 507(E), dated the 7th May, 2003 and number S.O.1252(E), dated the 8th November, 2004.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,
ರಿಚಾರ್ಡ್ ಲೋಬೋ
ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ
ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,
ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 99

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 94 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 31ನೇ ಮಾರ್ಚ್, 2005

2005ನೇ ಸಾಲಿನ ಫೆಬ್ರವರಿ 5ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.122(E) (No. F.No.17-6/2004-SD-IV] ದಿನಾಂಕ: 02.02.2005ನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF AGRICULTURE
(Department of Agriculture and Co-operation)
NOTIFICATION
New Delhi, the 2nd February, 2005

S.O. 122(E): In exercise of the powers conferred by section 5 of the Seeds Act, 1966 (54 of 1966), the Central Government, after consultation with the Central Seed Committee, being of the opinion that it is necessary and expedient to regulate the quality of the seeds of the varieties specified in column (3) of the Table below of the kinds specified in the corresponding entries in column (2) of the said Table, to be sold for the purpose of agriculture, hereby declares that the said varieties of seeds shall be the notified varieties for the whole of India, for the purposes of the said Act, for a period of fifteen years from the date of publication of this notification in the Official Gazette, namely:

TABLE

Serial No.	Kind	Variety
1.	Paddy	HKR-126
2.	Paddy	SYE-2001
3.	Paddy	Palam Dhan-957(IET-13795)
4.	Paddy	Sharavathi (IR-57773)
5.	Paddy	JR-503(Richa) (IET-16783)
6.	Paddy	Pusa Sugandh-5 (IET-17021)
7.	Paddy	Suruchi 5401 (MPH-5401)
8.	Paddy	Sugandhamati (IET-16775)
9.	Paddy	GR-9
10.	Paddy	PKV Makarand
11.	Paddy	PVK-SKL-3-11-25-30-36
12.	Paddy	Indira Dhan-1 (IET-15376) (R636-405)
13.	Barley	NDB-1173
14.	Barley	VL Barley-56
15.	Wheat	Palam (HPW-147)
16.	Wheat	Chandrika (HPW-184)
17.	Wheat	VL Gehun-802
18.	Wheat	Urja (HD-2864)
19.	Wheat	MACS-6145
20.	Sorghum	Parbhani Moti (PVR-396/SPV-1411)
21.	Fodder Sorghum	Gujarat Fodder Sorghum-5
22.	Maize	Pratap Makka-3 (EC-3108)
23.	Maize	Super Kohinoor (BISCO-2418)
24.	Maize	Win Orange Sweet Corn
25.	Maize	BIO 9636 (BIO 92136)

Serial No.	Kind	Variety
26.	Maize	VL Baby Corn-1 (VL-78)
27.	Maize	DK-984 (2784)
28.	Maize	IC-8209 (72A)
29.	Maize	Vivek Maize Hybrid-15 (FH-3176)
30.	Maize	Vivek Maize Hybrid-17 (FH-3186)
31.	Maize	Azad Kamal (R 9803)
32.	Pearl Millet	PROAGRO- 9444 (MSH-118)
33.	Pearl Millet	Parbhani Sampada (PPC-6)
34.	Groundnut	Kadiri-5
35.	Groundnut	Kadiri-6
36.	Groundnut	Prutha (Dh-86)
37.	Groundnut	RG-382
38.	Linseed	BINWA (KL-210)
39.	Soybean	Palam Soya (P-30-1-1)
40.	Soybean	TAMS-38
41.	Sunflower	PROSUN-09 (PRO-009)
42.	Sunflower	KBSH-41
43.	Sunflower	KBSH-42
44.	Sunflower	DRSF-108
45.	Red Clover	PRC-3
46.	Indian Mustard	CS-54 (CS 614-4-1-4)
47.	Niger	NRS 96 1
48.	Niger	Birsa Niger-2 (BNS-8)
49.	Safflower	Phule Kusuma (JLSF-414)
50.	Sunhemp	Narendra Sanai-1
51.	Sunhemp	Sailash (SH-4)
52.	Daincha	Pant Daincha-1
53.	Daincha	DH-2
54.	Mesta	Nirmal (MT-150)
55.	French bean	Kailash (SRC-74)
56.	Chickpea	Harvana Kabuli Chana-2 (HK 94-134)
57.	Pigeon pea	Malaviya Chamatkar (MAL-13)
58.	Horse gram	Pratap Kulthi-1 (AK-42)
59.	Moth bean	CAZRI Moth-3 (CZM-99)
60.	Rice bean	Bidhan Rice Bean-2 (KRB-4)
61.	Cluster bean (Guar)	Surya (RGM-112)
62.	Cotton	RBDV-7 (Pratap Kapi-1)
63.	Cotton	CICR-2 (CISAA-2) (GMS based Hybrid)
64.	Cotton	Shresth (CSHH-198)
65.	Cotton	PH-348 (Yamuna)
66.	Cotton	PA-402
67.	Cotton	Phule LJA-794
68.	Cotton	Mahabeej-106
69.	Cotton	Mahabeej DH-986
70.	Tossa jute	Subala (S-19)
71.	White jute	JRC 80 (Mitali White)
72.	Oat	Bundel Jai 992 (JHO 99-2)
73.	Setaria grass	Setaria-92
74.	Tall Fescue grass	Hima-4
75.	Guinea grass	Bundel Guinea-1 (JHGG 96-5)
76.	Sugarcane	Sweta (CoS 94270)

[F.No. 17-6/2004-SD-IV]

PREM NARAIN, Jt. Secy.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 100

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 92 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 2ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಫೆಬ್ರವರಿ 11ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.194(E)/ No. F.No. 48/2005/ F.No.178/ 14/ 2001-ITA-I] ದಿನಾಂಕ:11.02.2005ನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF FINANCE

(Department of Revenue)

(CENTRAL BOARD OF DIRECT TAXES)

NOTIFICATION

New Delhi, the 11th February, 2005

(Income-tax)

S.O. 194(E): In exercise of the powers conferred by clause (ii) of Sub-section (1) of section 80L of the Income-tax Act, 1961 (43 of 1961) the Central Government hereby specifies the following debentures, in the nature of bonds, namely:

(i) the Industrial Development Bank of India Regular Income Bond bearing distinctive numbers from 1 to 1691, of the face value of Rupees 10,000/- each; and

(ii) the Industrial Development Bank of India Floating Rate Bond bearing distinctive numbers from 1692 to 1851, of the face value of Rupees 10,000/- each,

issued by the Industrial Development Bank of India, Mumbai, a corporation established under section 3 of the Industrial Development Bank of India Act, 1964 (10 of 1964) in its public issue of bonds in Flexibonds 2-A Series, for the purposes of the said clause.

[Notification No. 48/2005/F.No.178/14/2001-ITA-I]

DEVI SHARAN SINGH, Under Secy.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಪಿ.ಆರ್. 101 ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 95 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 8ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಫೆಬ್ರವರಿ 6- ಫೆಬ್ರವರಿ 12, 2005ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(i)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ GSR.57 (E) [F.No. S.38012/3/2004-SSI] ದಿನಾಂಕ: 31.01.2005ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF LABOUR AND EMPLOYMENT

New Delhi, the 31st January, 2005

G.S.R. 57: Whereas certain draft Rules further to amend the Employee's State Insurance (Central) Rules, 1950 were published as required by sub-section (1) of section 95 of the Employee's State Insurance Act, 1948 (34 of 1948) vide notification of the Government of India in the Ministry of Labour and Employment No. G.S.R. 2627 dated the 5th October, 2004, in the Gazette of India, Part-II, Section 3, Sub-section (ii) dated the 16th October, 2004 for inviting objection or suggestion from any persons likely to be affected thereby till the expiry of the period of forty-five days from the date on which the copies of the Gazette of India, in which the said notification was published, were made available to the public.

And whereas, the copies of the said Gazette were made available to the public on the 16th October, 2004.

And whereas, objections and suggestions received from persons likely to be affected thereby have been considered by the Government.

Now, therefore, in exercise of the powers conferred by section 95 of the said Act, the Central Government, after consultation with Employee's State Insurance Corporation hereby makes the following rules further to amend the Employees' State Insurance (Central) Rules, 1950, namely:

1. (1) These Rules may be called the Employees' State Insurance (Central) (Amendment) rules, 2005.
   (2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Employees' State Insurance (Central) Rules, 1950, in rule 10, for sub-rule (2) the following shall be substituted namely:

"(2) The Annual Accounts relating to a financial year duly authenticated by the Financial Commissioner and the Director General and approved by the Standing Committee shall be submitted for audit to the Comptroller and Auditor General of India and the Audited Accounts together with the report of the Comptroller and Auditor General of India shall be placed for adoption at a meeting of the Corporation to be held before the tenth of December following the close of the financial year concerned.

Provided that the report of the Comptroller and Auditor General of India is received by the twentieth November, following the year to which it pertains."

[F.No. S-38012/3/2004-S.S.I]

SANJUKTA RAY, Under Secy.

Foot Note: The principal rules were published in the Gazette of India, Part-II, Section-3, Sub-section (i) vide Government of India, Ministry of Labour, Notification No. SRO 212 Dated: 22.06.1950 and subsequently amended by the following notification:

1. G.S.R. No. 80 Dated: 09.01.1960
2. G.S.R. No. 1200 Dated: 27.09.1960
3. G.S.R. No. 594 Dated: 29.03.1963
4. G.S.R. No. 240 Dated: 06.02.1964
5. G.S.R. No. 1834 Dated:18.12.1964
6. G.S.R. No. 474 Dated: 19.03.1965
7. G.S.R. No. 1082 Dated:29.06.1966
8. G.S.R. No. 545 Dated: 14.04.1967
9. G.S.R. No. 500 Dated:06.03.1968
10. G.S.R. No. 677 Dated:29.03.1968
11. G.S.R. No. 1106 Dated:22.05.1968
12. G.S.R. No. 2113 Dated:28.11.1968
13. G.S.R. No. 306 Dated:07.03.1974
14. G.S.R. No. 1122 Dated:01.10.1974
15. G.S.R. No. 56 Dated:23.12.1976
16. G.S.R. No. 60Dated:05.01.1982
17. G.S.R. No. 129 Dated:09.02.1987
18. G.S.R. No. 199 Dated:06.03.1990
19. G.S.R. No. 76 Dated: 22.01.1991
20. G.S.R. No. 368 Dated:27.03.1992
21. G.S.R. No. 522 Dated: 16.11.1996
22. G.S.R. No. 585 (E)Dated:23.12.1996
23. G.S.R. No. 225 Dated:21.04.1997
24. G.S.R. No. 226 Dated:22.04.1997
25. G.S.R. No. 185 Dated:01.09.1998
26. G.S.R. No. 129 Dated:08.04.2000
27. G.S.R. No. 210 Dated: 27.03.2001
28. G.S.R. No. 28 Dated: 02.01.2004
29. G.S.R. No. 127(E) Dated: 04.03.2004
30. G.S.R. No. 316 Dated: 18.09.2004

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

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ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 97 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 8ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಫೆಬ್ರವರಿ 28ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O. 266(E) [No.67/2005/F.No.19 (Part-II) FB/2005-TPL] ದಿನಾಂಕ: 28.02.2005ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF FINANCE
(Department of Revenue)
(CENTRAL BOARD OF DIRECT TAXES)
NOTIFICATION
New Delhi, the 28th February, 2005
INCOME-TAX

S.O.266(E): In exercise of the powers conferred by section 295 of the Income-tax Act, 1961 (43 of 1961), the Central Board of Direct Taxes hereby makes the following rules further to amend the Income-tax Rules, 1962, namely:

1. (1) These Rules may be called the Income-tax (Sixth Amendment) Rules, 2005.
   (2) They shall come into force from the 2nd day of April, 2005.
2. In the Income-tax Rules, 1962, for Appendix I, the following shall be substituted, namely:

'APPENDIX-I
[Effective from assessment year 2006-2007]
[See rule 5]
TABLE OF RATES AT WHICH DEPRECIATION IS ADMISSIBLE

Block of assets			Depreciation allowance as percentage of written down value
1			2
	PART-A TANGIBLE ASSETS		
I.	**BUILDING [See Notes 1 to 4 below this Table]**		
(1)	Buildings which are used mainly for residential purposes except hotels and boarding houses		5
(2)	Buildings other than those used mainly for residential purposes and not covered by sub-items (1) above and (3) below		10
(3)	Buildings acquired on or after the 1st day of September, 2002 for installing machinery and plant forming part of water supply project or water treatment system and which is put to use for the purpose of business of providing infrastructure facilities under clause (i) of sub-section (4) of section 80-1A.		100
(4)	Purely temporary erections such as wooden structures		100
II.	**FURNITURE AND FITTINGS**		
	Furniture and fittings including electrical fittings [See Note 5 below this Table}		10
III.	**MACHINERY AND PLANT**		
(1)	Machinery and plant other than those covered by sub-items (2), (3) and (8) below:		15
(2)	Motor cars, other than those used in a business of running them on hire, acquired or put to use on or after the 1st day of April, 1990		15
(3)	(i)	Aeroplanes-Acroengines	40
	(ii)	Motor buses, motor lorries and motor taxis used in a business of running them on hire	30
	(iii)	Commercial vehicle which is acquired by the assessee on or after the 1st day of October, 1998, but before the 1st day of April, 1999 and is put to use for any period before the 1st day of April, 1999 for the purposes of business or profession in accordance with the third proviso to clause (ii) of sub-section (1) of section 32 [See Note 6 below this Table]	40
	(iv)	New commercial vehicles which is acquired on or after the 1st day of October, 1998 but before the 1st day of April, 1999 in replacement of condemned vehicle of over 15 years of age and is put to use for any period before the 1st day of April, 1999 for the purposes of business or profession in accordance with third proviso to clause (ii) of section (1) of section 32 [See Note 6 below this Table]	60

1			2
	(v)	New commercial vehicle which is acquired on or after the 1st day of April, 1999 but before the 1st day of April, 2000 in replacement of condemned vehicle of over 15 years of age and is put to use before the 1st day of April, 2000 for the purposes of business or profession in accordance with the second proviso to clause (ii) of sub-section (1) of section 32 [See Note 6 below this Table]	60
	(vi)	New commercial vehicle which is acquired on or after the 1st day of April, 2001 but before the 1st day of April, 2002 and is put to use before the 1st day of April, 2002 for the purposes of business or profession [See Note 6 below this Table]	50
	(vii)	Moulds used in rubber and plastic goods factories	30
	(viii)	Air pollution control equipment, being-	
	(a)	Electrostatic precipitation systems	100
	(b)	Felt-filter systems	
	(c)	Dust collector systems	
	(d)	Scrubber-counter current/venturi/ packed bed/ cyclonic scrubbers	
	(e)	Ash handling system and evacuation system	
	(ix)	Water pollution control equipment, being-	
	(a)	Mechanical screen systems	100
	(b)	Aerated detritus chambers (including air compressor)	
	(c)	Mechanically skimmed oil and grease removal systems	
	(d)	Chemical feed systems and flash mixing equipment	
	(e)	Mechanical flocculators and mechanical reactors	
	(f)	Diffused air/ mechanically aerated activated sludge systems	
	(g)	Aerated lagoon systems	
	(h)	Biofilters	
	(i)	Methanc-recovery anaerobic digester systems	
	(j)	Air floatation systems	
	(k)	Air/ steam stripping systems	
	(l)	Urea Hydrolysis systems	
	(m)	Marine outfall systems	
	(n)	Centrifuge for dewatering sludge	
	(o)	Rotating biological contractor or bio-disc	
	(p)	Ion exchange resin column	
	(q)	Activated carbon column	
(x)	(a)	Solidwaste, control equipment being- caustic/ lime/ chrome/ mineral/ cryolite recovery systems	100
	(b)	Solidwaste recycling and resource recovery systems	
(xi)	Machinery and plant, used in semi-conductor industry covering all integrated circuits (ICs) (excluding hybrid integrated circuits) ranging from small scale integration (SSI) to large scale integration/ very large scale integration (LSI/ VLSI) as also discrete semi conductor devices such as diodes, transistors, thyristors, triacs, etc., other than those covered by entries (viii). (ix) and (x) of this sub-time and sub-item (8) below.		30

1			2
(xia)	Life saving medical equipment, being-		40
	(a)	D.C. Defibrillators for internal use and pace makers	
	(b)	Haemodialysors	
	(c)	Heart lung machine	
	(d)	Cobalt Therapy Unit	
	(e)	Colour Doppler	
	(f)	SPECT Gamma Camera	
	(g)	Vascular Angiography System including Digital Subtraction Angiography	
	(h)	Ventilator used with anaesthesia apparatus	
	(i)	Magnetic Resonance Imaging System	
	(j)	Surgical Laser	
	(k)	Ventilator other than those used with anaesthesia	
	(l)	Gamma knife	
	(m)	Bone marrow Transplant Equipment including silastic long standing intravenous catheters for chemotherapy	
	(n)	Fibre optic endoscopes including, Paediatric resectoscope/ audit resecetoscope, Peritoneoscopes, Arthoscope, Microlaryngoscope, Fibreoptic Flexible Nasal Pharyngo Bronchoscope, Fibreoptic Flexible Laryngo Bronchoscope, Vidoe Laryngo Bronchoscope and Video Oesophago Gastroscope, Stroboscope, Fibreoptic Flexible Oescophago Gastroscope	
	(o)	Laparoscope (single incision)	
(4)	Containers made of glass or plastic used as re-fills		50
(5)	Computers including computer software [See note 7 below this Table]		60
(6)	Machinery and plant, used in weaving processing and garment sector of textile industry, which is purchased under TUFS on or after the 1st day of April, 2001 but before the 1st day of April, 2004 and is put to use before the 1st day of April, 2004 [See Note 8 below this Table]		50
(7)	Machinery and plant, acquired and installed on or after the 1st day of September, 2002 in a water supply project or a water treatment system and which is put to use for the purpose of business of providing infrastructure facility under clause (i) of sub-section (4) of section 80-1A [See Notes 4 and 9 below this Table]		100
(8)	(i)	Wooden parts used in artificial silk manufacturing machinery	100
	(ii)	Cinematograph films-bulbs of studio lights	
	(iii)	Match factories-Wooden match frames	
	(iv)	Mines and quarries:	
		(a) Tubs winding ropes, haulage ropes and sand stowing pipes	
		(b) Safety lamps	
	(v)	Salt works-Salt pans, reservoirs and condensers, etc., made of earthy, sandy or clayey material or any other similar material	
	(vi)	Flour mills-Rollers	80
	(vii)	Iron and steel industry-Rolling mill rolls	
	(viii)	Sugar works-Rollers	
	(ix)	Energy saving devices, being:	
	A.	**Specialised boilers and furnances:**	
	(a)	Ignifluid/ fluidized bed boilers	80
	(b)	Flameless furnances and continuous pusher type furnances	
	(c)	Fluidized bed type heat treatement furnaces	

	1		2
	(d)	High efficiency boilers (thermal efficiency higher than 75 percent in case of coal fired and 80 percent in case of oil/ gas fired boilers)	
	B.	**Instrumentation and monitoring system for monitoring energy flows:**	
	(a)	Automatic electrical lond monitoring systems	80
	(b)	Digital heat loss meters	
	(c)	Micro-processor based control systems	
	(d)	Infra-red thermography	
	(e)	Meters for measuring heat losses, furnance oil flow, steam flow, electric energy and power factor meters	
	(f)	Maximum demand indicator and clamp on powers meters	
	(g)	Exhaust gases analyser	
	(h)	Fuel oil pump test bench	
	C.	**Waste heat recovery equipment:**	
	(a)	Economisers and feed water heaters	80
	(b)	Recuperators and air pre-heaters	
	(c)	Heat pumps	
	(d)	Thermal energy wheel for high and low temperature waste heat recovery	
	D.	**Co-generation systems:**	
	(a)	Back pressure pass out, controlled extraction, extraction-cum-condensing turbines for co-generation along with pressure boilers	80
	(b)	Vapour absorption refrigeration systems	
	(c)	Organic ranking cycle power systems	
	(d)	Low inlet pressure small steam turbines	
	E.	**Electrical equipment:**	
	(a)	Shunt capacitors and sysnchoronous condenser systems	
	(b)	Automatic power cut off devices (relays) mounted on individual moters	
	(c)	Automatic voltage controller	
	(d)	Power factor controller for AC motors	
	(e)	Solid state devices for controlling motor speeds	
	(f)	Thermally energy-efficient stenters (which require 800 or less kilocalories of heat to evaporate one kilogram of water)	
	(g)	Series compensation equipment	
	(h)	Flexible AC Transmission (FACT) devices-Thyristor controlled series compensation equipment	
	(i)	Time of Day (ToD) energy meters	
	(j)	Equipment to establish transmission highways for National Power Grid to facilitate transfer of surplus power of one region to the deficient region.	
	(k)	Remote terminal units/ intelligent electronic devices, computer hardware/ software, router/ bridges, other required equipment and associated communication systems for supervisory control and data acquisition systems, energy management systems and distribution management systems for power transmission systems	
	(l)	Special energy meters for Availability Based Tariff (ABT)	

1			2
	F.	**Burners:**	
	(a)	0 to 10 percent excess air burners	80
	(b)	Emulsion burners	
	(c)	Burners using air with high pre-heat temperature (above 300^0C)	
	G.	**Other equipment:**	
	(a)	Wet air oxidation equipment for recovery of chemicals and heat	80
	(b)	Mechnical vapour recompressors	
	(c)	Thin film evaporators	
	(d)	Automatic micro-processor based load demand controllers	
	(e)	Coal based producer bas plants	
	(f)	Fluid drives and fluid couplings	
	(g)	Turbo charges/ super-charges	
	(h)	Sealed radiation sources for radiation processing plants	
	(x)	Gas cylinders including valves and regulators	60
	(xi)	Glass manuafacturing concerns-Direct fire glass melting furnaces	60
	(xii)	Mineral oil concerns:	60
	(a)	Plant used in field operations (above ground) distribution-Returnable packages	
	(b)	Plant used in field operations (below ground), but not including kerbside pumps including under ground tanks and fittings used in field operations (distribution) by mineral oil concerns	
	(xii)	Renewable energy devices being-	80
	(a)	Flat plate solar collectors	
	(b)	Concentrating and pipe type solar collectors	
	(c)	Solar cookers	
	(d)	Solar water heaters and systems	
	(e)	Air/ gas fluid heating systems	
	(f)	Solar crop driers and systems	
	(g)	Solar refrigeration, cold storages and air conditioning systems	
	(h)	Solar steels and desalination systems	
	(i)	Solar power generating systems	
	(j)	Solar pumps based on solar-thermal and solar-photovoltaic conversion	
	(k)	Solar-photovoltaic modules and panels for water pumping and other applications	
	(l)	Wind mills and any specially designed devices which run on wind mills	
	(m)	Any special devices including electric generators and pumps running on wind energy	
	(n)	Biogas-plant and biogas-engines	
	(o)	Electrically operated vehicles including battery powered or fuel-cell powered vehicles	
	(p)	Agricultural and municipal waste conversion devices producing energy	
	(q)	Equipment for utilising ocean waste and thermal energy	
	(r)	Machinery and plant used in the manufacture of any of the above sub-items	
(9)	(i)	Books owned by assessees carrying on a profession-	
	(a)	Books, being annual publications	100

1			2
	(b)	Books, other than those covered by entry (a) above	60
	(ii)	Books owned by assessees carrying on business in running lending libraries	100
IV.	**SHIPS**		
(1)	Ocean-going ships including dredgers, tugs, barges, survey launches and other similar ships used mainly for dredging purposes and fishing vessels with wooden hull		20
(2)	Vessels ordinarily operating on inland waters, not covered by sub-item (3) below		20
(3)	Vessels ordinarily operating on inland waters being speed boats [See Note 10 below this Table]		20
PART-B INTANGIBLE ASSETS			
Know-how, patents, copyrights, trademarks, licences, franchises or any other business or commercial rights of similar nature.			25

Notes:

1. "Buildings" include roads, bridges, culverts, wells and tubewells.
2. A building shall be deemed to be a building used mainly for residential purposes, if the built up floor area thereof used for residential purposes is not less than sixty-six and two-third percent of its total built-up floor area and shall include any such building in the factory premises.
3. In respect of any structure or work by way of renovation or improvement in or in relation to a building referred to in Explanation 1 of clause (ii) of sub-section (1) of section 32, the percentage to be applied will be the percentage specified against sub-item (1) or (2) of item 1 as may be appropriate to the class of building in or in relation to which the renovation or improvement is effected. Where the structure is constructed or the work is done by way of extension of any such building, the percentage to be applied would be such percentage as would be appropriate, as if the structure or work constituted a separate building.
4. Water treatement system includes system for desalination, demineralisation and purification of water.
5. "Electrical fittings" include electrical wiring, switches, sockets, other fittings and fans, etc.
6. "Commercial vehicle" means "heavy goods vehicle", "heavy passenger motor vehicle", "light motor vehicle", "medium goods vehicle" and "medium passenger motor vehicle" but does not include "maxi-cab", "motor-cab", "tractor" and "road-roller". The expressions "heavy goods vehicle", "heavy passenger motor vehicle", "light motor vehicles", "medium goods vehicle", "medium passenger motor vehicle", "maxi-cab", "motor-cab", "tractor" and "road-roller" shall have the meanings respectively assigned to them in section 2 of the Motor Vehicles Act, 1988 (59 of 1988).
7. "Computer software" means any computer program recorded on any disc, tape, perforated media or other information storage device.
8. "TUFS" means Technology Upgradation Fund Scheme announced by the Government of India in the form of a Resolution of the Ministry of Textiles vide No. 28/1/99-CTI of 31.03.1999.
9. Machinery and plant includes pipes needed for delivery from the source of supply of raw water to the plant and from the plant to the storage facility.
10. "Speed boat" means a motor boat driven by a high speed internal combustion engine capable of propelling the boat at a speed exceeding 24 kilometers per hour in still water and so designed that when running at a speed, it will plane, i.e., its bow will rise from the water.'.

[Notification No. 67/2005/F.No. 19 (Part-II)/FB/2005-TPL]

A. SREENIVASA RAO, Under Secy.

Note: The principal rules were published vide Notification No. S.O. 969(E), Dated the 26th March, 1962 and last amended by Income-tax (fifth Amendment) Rules, 2005 vide Notification No. S.O. 232(E) dated 17th February, 2005.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

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ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 96 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 8ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಫೆಬ್ರವರಿ 25ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(i)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ G.S.R.105(E) [No.X-11014/3/2004-DMS & PFA] ದಿನಾಂಕ: 24.02.2005ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF HEALTH AND FAMILY WELFARE
NOTIFICATION
New Delhi, the 24th February, 2005

G.S.R. 105(E): The following draft of certain rules further to amend the Drugs and cosmetics Rules, 1945 which the Central Government proposes to make, after consultation with the Drugs Technical Advisory Board, in exercise of the powers conferred by Section 12 and Section 33 of the Drugs and Cosmetics, Act, 1940 (23 of 1940), is hereby published as required by the said sections for the information of all persons likely to be affected thereby and notice is hereby given that the said draft rules will the taken into consideration after the expiry of a period of forty-five days from the date on which the copies of the Official Gazette in which this notification is published, are made available to the public;

Any objection or suggestions which may be received from any person with respect to the said draft rules before the expiry of the period as specified above will be taken into consideration by the Central Government which may be addressed to the Secretary (Health), Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi-110011.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (Amendment) Rules, 2005.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, for Schedule H, the following Schedule shall be substituted, namely:

SCHEDULE-II
(See Rules 65 and 97)
PRESCRIPTION DRUGS

1.	Abacavir	2.	Abciximab
3.	Acamprosate Calcium	4.	Acebutol Hydrochloride
5.	Aclarubicin Injection	6.	AlcLometasone Dipropionate
7.	Actilyse	8.	Acyclovir
9.	Adensine	10.	Adrenocorticotrophgic Hormone (Acth)
11.	Alendronate Sodium	12.	Allopurinol
13.	Alphachymotrypsin	14.	Alprazolam
15.	Alprostadil	16.	Amantadinc Hydrochloride
17.	Amifostine	18.	Amikacin
19.	Amiloride Hydrochloride	20.	Amineptine
21.	Aminoglutethimide	22.	Aminosalicylic acid
23.	Amiodarone Hydroxhloride	24.	Amitriptyline its salts
25.	Amlodipine Besylate	26.	Amoscanate
27.	Amoxapine	28.	Amrinone Lactate
29.	Analgin	30.	Androgenic Anabolic, Oestrogenic & Progestational Substances
31.	Antibiotics	32.	Apraclonidine
33.	Aprotinin	34.	Organic Compound of Arsenic for Injection
35.	Artecther	36.	Artemether
37.	Artesunate	38.	Articaine Hydrochloride
39.	Atenolol	40.	Atracurium Besylate Injection
41.	Atorvastatin	42.	Auranofin
43.	Azathioprine	44.	Aztreonam
45.	Acampicillin	46.	Baclofen
47.	Balsalazide	48.	Bambuterol

49.	Barbituric Acid, its Salts/ Derivatives of Barbituric Acid	50.	Basiliximab
51.	Benazepril Hydrochloride	52.	Benidipine Hydrochloride
53.	Benserazide Hydrochloride	54.	Betahistine Dihydrochloride
55.	Bethanidine Sulphate	56.	Bezafibrate
57.	Bicalutamide	58.	Biclotymol
59.	Bifonazole	60.	Bimatoprost
61.	Biperiden Hydrochloride	62.	Biphenyl Acetic Acid
63.	Bitoscanate	64.	Bleomycin Oil Suspension
65.	Primonidine Tartrate	66.	Bromhexine Hydrochloride
67.	Bromocriptine Mesylate	68.	Budesonide
69.	Bulaquine	70.	Bupivacaine Hydrochloride
71.	Bupropion	72.	Buspirone
73.	Butenafine Hydrochloride	74.	Butorphanol Tartrate
75.	Cabergoline	76.	Calcium Dobesilate
77.	Candesartan	78.	Capecitabine
79.	Captopril	80.	Carbidopa
81.	Carbocisteine	82.	Carboplatin Injection
83.	Carboquone	84.	Carisoprodol
85.	L-Carnitine	86.	Carteolol Hydrochloride
87.	Carvedilol	88.	Cefadroxyl
89.	Cefatoxime Sodium	90.	Cefazolin Sodium
91.	Cefdinir	92.	Cefepime Hydrochloride
93.	Cefetamet Pivoxil	94.	Cefpirome
95.	Cefpodoxime Poxetil	96.	Ceftazidime Pentahydrate
97.	Ceftizoxime Sodium Sterile	98.	Cefuroxime
99.	Celecoxib	100.	Centchroman
101.	Centbutindole	102.	Centpropazine
103.	Chlordianepoxide its Salts	104.	Chlormezanone
105.	Chlopromazine its Salts	106.	Chlorzoxazone
107.	Ciclopirox Olamine	108.	Cimetidine
109.	Cinnarizine	110.	Ciprofloxacin Hydrochloride Monohydrate/ Lactate
111.	Citalopram Hydrobromide	112.	Clarithromycin
113.	Clavulanic Acid	114.	Clidinium Bromide
115.	Clindamycin	116.	Clobazam
117.	Clobetasol Proenate	118.	Clobetasone 17-Butyrate
119.	Clofazimine	120.	Clofibrate
121.	Clonazepam	122.	Clonidine Hydrochloride
123.	Clopamide	124.	Clopidogrel Bisulphate
125.	Clostebol Acetate	126.	Clotrimazole
127.	Clozapine	128.	Codeine, Its Salts & Derivatives
129.	Colchicine	130.	Corticosteroids, their Esters, Their Derivatives & Their Dosage Forms
131.	Cotrimoxazole	132.	Cyclandelate
133.	Cyclosporin Oral Solution	134.	Daclizumab
135.	Danazol	136.	Dapsone, its Salts and Derivatives
137.	Desloratadine	138.	Desogestrole
139.	Dexrazoxane	140.	Dextranomer
141.	Dextropropoxyphene, its Salts	142.	Diazapam
143.	Diazoxide	144.	Diclofenac Sodium/ Potassium/ Acid
145.	Didanosine	146.	Digoxine
147.	Dilazep Hydrochloride	148.	Diltiazem

149.	Dinoprostone	150.	Diphenoxylate, its Salts
151.	Dipivefrin Hydroxhloride	152.	Di-Sodium Pamidronate
153.	Disopyramide	154.	Docetaxel
155.	Domperidone	156.	Donepezil Hydroxhloride
157.	Dopamine Hydroxhloride	158.	Dothiepin Hydroxhloride
159.	Doxapram Hydrochloride	160.	Doxazosin Mesylate
161.	Doxepin Hydrochloride	162.	Drotrecogin-Alpha
163.	Ebastine	164.	Econozole
165.	Efavirenz	166.	Enalapril Meleate
167.	Enfenamic Acid	168.	Epinephrine, its Salts
169.	Epirubicine Injection	170.	Eptifibatide
171.	Ergot, Alkaloids of, Whether Hydrogenated or Not, Their Homologues, Salts	172.	Esomeprazole
173.	Estradiol Succinate	174.	Estramustine Phosphate Capsule
175.	Etanercept	176.	Ethacridine Lactate
177.	Ethambutol Hydrochloride	178.	Ethamsylate
179.	Ethinyloestradiol	180.	Ethionamide
181.	Etidronate Disodium	182.	Etodolac
183.	Etomidate	184.	Etoposide Capsule and Injection
185.	Exemestane	186.	Famciclovir
187.	Famotidine	188.	Fenofibrate
189.	Fexofenadine	190.	Finasteride
191.	Flavoxate Hydrochloride	192.	Fludarabine
193.	Flufenamic Acids, its Salts/ esters	194.	Flunarizine Hydrochloride
195.	Fluoxetine Hydrochloride	196.	Flupenthixol
197.	Fluphenazine Enanthate and Decanoate		
198.	Flurazepam	199.	Flurbiprofen
200.	Flutamide	201.	Fluticasone Propionate
202.	Fluvoxamine Maleate	203.	Formestane
204.	Fosinopril Sodium	205.	Fosphenytoin Sodium
206.	Fotemustine	207.	Gabapentin
208.	Calanthamine Hydrobromide	209.	Gallamine, its Salts, its Quaternary Compound
210.	Gancyclovir	211.	Ganirelix
212.	Gatifloxacin	213.	Gemcitabine
214.	Gemfibrozil	215.	Gemtuzumab
216.	Genodeoxycholic Acid	217.	Gliclazide
218.	Glimepiride	219.	Glucagon
220.	Glycopyrrolate	221.	Goscreline Acetate
222.	Gosereline Acetate	223.	Granisetron
224.	Guanethidine	225.	Gugulipid
226.	Halogenated Hydroxyquinolines	227.	Haloperidol
228.	Heparin	229.	Hepatitis B. Vaccine
230.	Hyaluronidase	231.	Hydrocorisone 17-Butyrate
232.	Hydrotalcite	233.	Hydroxyzine, its Salts
234.	Ibuprofen	235.	Idebenone
236.	Iindapamide	237.	Imipramine, its Salts
238.	Indinavir Sulphate	239.	Indomethacin, its Salts
240.	Insulin Human	241.	Interferon Injection
242.	Intravenous Fat Emulsion	243.	Iobitridol
244.	Iohexol Injection	245.	Lopamidol Injection
246.	Iomeprol	247.	Lopromide
248.	Irbesartan	249.	Irinotecan Hydrochloride

250.	Iron Preparation for Parenteral use	251.	Isepamicine
252.	Isocarboxside	253.	Isoflurane
254.	Isonicotnic Acid Hydrazine and other-Hydragine Derivatives of Isonicotinic Acid	255.	Isosorbide Dinitrate/ Mononitrate
256.	Isotretinoin	257.	Isoxsuprinc
258.	Itopride	259.	Ketamine Hydrochloride
260.	Ketoconazole Acetate	261.	Ketoprofen
262.	Ketorolac Tromethamine	263.	Labetalol Hydrochloride
264.	Lacidipine	265.	Lamivudine
266.	Lamotrigine	267.	Latanoprost
268.	Lefunormide	269.	Lercanidipine Hydrochloride
270.	Letrozole	271.	Leuprolide Acetate
272.	Levarterenol, it Salts	273.	Levobunolol
274.	Levocetirizine	275.	Levodopa
276.	Levofloxacin	277.	Levovist
278.	Lidoflazine	279.	Linezolid
280.	Lithium Carbonate	281.	Lofepramine Decanoate
282.	Loperamide	283.	Lorazepam
284.	Losartan Potassium	285.	Loteprednol
286.	Lovastatin	287.	Loxapine
288.	Mebendazole	289.	Mebeverine Hydrochloride
290.	Medroxy Progesterone Acetate Tablets	291.	Mefenamic Acid, its Salts, its Esters, their Salts
292.	Mefloquine Hydrochloride	293.	Megestrol Acetate
294.	Meglumine locarmate	295.	Melagenina Lotion
296.	Melitracen Hydrochloride	297.	Meloxicam
298.	Mephenesin, its Esters	299.	Mephentermine
300.	Meropenam	301.	MEsterolone
302.	Metaxalone	303.	Methicillin Sodium
304.	Methocarbamol	305.	Metoclopramide
306.	Metoprolol Tartrate	307.	Metrizamide
308.	Metronidazole	309.	Mexiletine Hydrochloride
310.	Mianserin Hydrochloride	311.	Miconazole
312.	Midazolam	313.	Mifepristone
314.	Milrinone Lactate	315.	Miltefosine
316.	Minocycline	317.	Minoxidil
318.	Mirtazapine	319.	Misoprostol
320.	Mitoxantrone Hydrochloride	321.	Mizolastine
322.	Moclobemide	323.	Mometasone Furoate
324.	Montelukast Sodium	325.	Morphazinamide Hydrochloride
326.	Mosapride	327.	Moxifloxacin
328.	Mycophenolate Mofetil	329.	Nadifloxacin
330.	Nadolol	331.	Nafareline Acetate
332.	Nalidixic Acid	333.	Naproxen
334.	Narcotic Drugs Listed in Narcotic Drugs & Psychotropic Substances Act, 1985	335.	Natamycin
336.	Nateglinide	337.	N-Butyl-2-Cyanoacrylate
338.	Nebivolol	339.	Nebumetone
340.	Nelfinavir Mesilate	341.	Netilmicine Sulphate
342.	Nevirapine	343.	Nicergoline
344.	Nicorandil	345.	Nifedipine
346.	Nimesulide	347.	Nimustine Hydrochloride
348.	Nitrazepam	349.	Nitroglycerin Injection

350.	Norethisterone Enanthate Injection	351.	Norfloxacin
352.	Octylonium Bromide	353.	Ofloxacin
354.	Olanzapine	355.	Omidazole
356.	Orphenadrine, its Salts	357.	Orthoclone Sterile
358.	Oxazepam	359.	Oxazolidine, its Salts
360.	Oxcarbazepine	361.	Oxethazaine Hydrochloride
362.	Oxiconazole	363.	Oxolinic Acid
364.	Oxprenolol Hydrochloride	365.	Oxybutynin Chloride
366.	Oxyfedrine	367.	Oxymetazoline
368.	Oxyphenbutazone	369.	Oxytocin
370.	Ozothine	371.	Pancuronium Bromide
372.	Pantoprazole	373.	Para-Amino Benzene Sulphonamide, its Salts & Derivatives
374.	Para-Amino Salicylic Acid, its Salts, its Derivatives	375.	Parecoxib
376.	Paroxetine Hydrochloride	377.	D-penicillamine
378.	Pentazocine	379.	Pentoxifylline
380.	Pepleomycin Injection	381.	Phenolzine, its Salts
382.	Phenobarbital	383.	Phenothiazine, Derivatives of and Salts of its Derivatives
384.	Phenylbutazine, its Salts	385.	Pimozide
386.	Pindolol	387.	Pioglitazone Hydrochloride
388.	Piracetam	389.	Piroxicam
390.	Pituitory Gland, Active Principles of, not otherwise specified in this Schedule and their Salts	391.	Polidocanol Injection
393.	Polestradiol Phosphate Injection	393.	Poractant Alfa
394.	Praziquantel	395.	Prednimustine Tablets
396.	Prenisolone Stearoylglycolate	397.	Prenoxdiazine Hydrochloride
398.	Promazine Hydrochloride	399.	Promegestone
400.	Propafenon Hydrochloride	401.	Propanolol Hydrochloride
402.	Propofol Injection	403.	Protristyline Hydrochloride
404.	Pyrazinamide	405.	Pryvinium its, Salts
406.	Quetiapine Fumerate	407.	Quinapril
408.	Quinidine Sulphate	409.	Rabeprazole
410.	Racecadotril	411.	Raloxifene Hydrochloride
412.	Ranitidine	413.	Rauwolfia, Alkaloids of, their Salts, Derivatives of the Alkaloids or Rauwolfia
414.	Reboxetine	415.	Repaglinide
416.	Reproterol Hydrochloride	417.	Rilmenidine
418.	Riluzole	419.	Risperidone
420.	Ritonavir	421.	Ritodrine Hydrochloride
422.	Rituximab	423.	Rivastigmine
424.	Rocuronium Bromide	425.	Ropinirole
426.	Rosoxacin	427.	Rosiglitazone Maleate
428.	Salbutamol Sulphate	429.	Salicyl1-Azo-Sulphapyridine
430.	Salmon Calcitonin	431.	Saquinavir
432.	Satranidazole	433.	Septopal Beads & Chains
434.	Serratiopeptidase	435.	Sertraline Hydrochloride
436.	Sibutramine Hydroxhloride	437.	Sildenafil Citrate
438.	Simvastatin	439.	Sirolimus
440.	Sisomicin Sulphate	441.	S-Neominophagen-C Injection
442.	Sodium Picosulphate	443.	Sodium Cromoglycate

444.	Sodium Hyaluronate Solution	445.	Sodium Valproate
446.	Sodium and Maglumine Iothalamates	447.	Somatostatin
448.	Somatotropin	449.	Sotalol
450.	Sparfloxacin	451.	Spectinomycin Hydrochloride
452.	Spironolactone	453.	Stavudine
454.	Sucralfate	455.	Sulphadoxine
456.	Sulphamethoxine	457.	Sulphamethoxypyridazine
458.	Sulphaphenazole	459.	Sulpiride
460.	Sulprostone Hydrochloride	461.	Sumatriptan
462.	Tacrine Hydrochloride	463.	Tamsulosin Hydrochloride
464.	Trapidil	465.	Tegaserod Maleate
466.	Teicoplanin	467.	Telmisartan
468.	Temozolamide	469.	Terazosin
470.	Terbutaline Sulphate	471.	Terfenadine
472.	Terizidone	473.	Terlipressin
474.	Testosterone Undecoanoate	475.	Terafolol Hydrochloride
476.	Thalidomide	477.	Thiacetazone
478.	Thiocolchicoside	479.	Thiopropazate, its Salts
480.	Thymogene	481.	Thymosin-Alpha 1 Injection
482.	Tiaprofenic Acid	483.	Tibolone
484.	Timolol Maleate	485.	Tinidazole
486.	Tabramycin	487.	Tolfenamic Acid
488.	Topiramate	489.	Topotecan Hydrochloride
490.	Tranexamic Acid	491.	Tranycypromine, its Salts
492.	Trazodone	493.	Tretinoin
494.	Trifluperazine	495.	Trifluperidol Hydrochloride
496.	Triflusal	497.	Trimetazidine Dihydrochloride
498.	Trimipramine	499.	Tripotassium Dicitrate Bismuthate
500.	Tromantadine Hydrochloride	501.	Urokinase
502.	Valdecoxib	503.	Valsartan
504.	Vasopressin	505.	Vecuronium Bromide Injection
506.	Venlafaxine	507.	Verapamil Hydrochloride
508.	Verteporfin	509.	Vindesine Sulphate
510.	Vinorelbine Tatrate	511.	Xipamide
512.	Zidovudine Hydrochloride	513.	Ziprasidone Hydrochloride
514.	Zoledronic Acid	515.	Zolpidem
516.	Zopiclone	517.	Zuclopenthixol

Note:

1. Preparations exempted under proviso to para 2 of Note to Schedule X shall also be covered by this Schedule.
2. Preparations containing the above substances excluding those intended for topical or external use (except opthalmic and ear/ nose preparations containing antibiotics and/ or steroids) are also covered by this Schedule. The inclusion of a substance in this Schedule does not imply or convey that the substance is exempted from the provisions of Rule 122A/ 122B".

[No. X-11014/3/2004-DMS & PFA]

RITA TEOTIA, Jt. Secy.

Foot Note: The Principal Rules were published in the Official Gazette vide notification No. F.28-10/45-H(1) Dated: 21.12.1945.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 108

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 23 ಕೇಶಾಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 2ನೇ ಮಾರ್ಚ್, 2005

2005ನೇ ಸಾಲಿನ ಜನವರಿ 12ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 1ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ The Delegated Legislation Provisions [Amendment] Act, 2004 (Act No.4 of 2005) ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

Bill No. LI-F of 2004

THE DELEGATED LEGISLATION PROVISIONS (AMENDMENT)

A

BILL

to amend certain Acts to implement the recommendations of the Committees on Subordinate Legislation regarding publication and laying of rules and other delegated legislation.

BE it enacted by Parliament in the Fifty-fifth Year of the Republic of India as follows:

1. This Act may be called the Delegated Legislation Provisions (Amendment) Act, Short title, 2004.

2. The enactments specified in the Schedule are hereby amended to the extent and in the manner mentioned in the third column thereof. Amendment of certain enactments.

THE SCHEDULE

(See Section 2)

Sl. No.	Short title	Amendments
1.	The Punjab Laws Act, 1872 (4 of 1872)	Section 50A shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature."
2.	The Central Provinces Laws Act, 1875 (20 of 1875)	Section 10 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
3.	The Oudh Laws Act, 1876 (18 of 1876)	Section 40 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made by the State Government under section 39 shall be laid, as soon as may be after it is made, before the State Legislature."
4.	The Indian Treasure-trove Act, 1878 (6 of 1878)	Section 19 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature."
5.	The Northern India Ferries Act, 1878 (17 of 1878)	Section 12 shall be re-numbered as sub-section (1) thereof, and-
		(a) in sub-section (1) as so re-numbered, for the words "make rules", the words "by notification in the Official Gazette, make rules" shall be substituted;

Sl. No.	Short title	Amendments
		(b) after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made under this Act by the Commissioner of a division or the officer appointed by the State Government shall be laid, as soon as may be after it is made, before the State Legislature".
6.	The Hackney-carriage Act, 1879 (14 of 1879)	Section 6 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made under this Act shall be laid, as soon as may be after it is made, before the State Legislature."
7.	The Obstructions in Fairways Act, 1881 (16 of 1881)	Section 8 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule."
8.	The Land Improvement Loans Act, 1883 (19 of 1883)	Section 10 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature."
9.	The Agriculturists' Loans Act, 1884 (12 of 1884)	In section 4, after sub-section (2), the following sub-section shall be inserted, namely:
		"(3) Every rule made by the State Government or a Board of Revenue or a Financial Commissioner under this Act shall be laid, as soon as may be after it is made, before the State Legislature."
10.	The Indian Tramways Act, 1886 (11 of 1886)	After section 24, the following section shall be inserted, namely:
	Rules to be laid before Parliament and State Legislature	"24A. (1) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

Sl. No.	Short title	Amendments
		(2) Every rule made by a State Government or a local authority or a promoter or a lessee under this Act shall be laid, as soon as may be after it is made, before the State Legislature."
11.	The Government Management of Private Estates Act, 1892 (10 of 1892)	Section 7 shall be re-numbered as sub-section (1) thereof, and-
		(a) in sub-section (1) as so re-numbered, for the words "may make any rules", the words "may, by notification in the Official Gazette, make rules" shall be substituted;
		(b) after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made and every order issued by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature."
12.	The Reformatory Schools Act, 1897 (8 of 1897)	In section 26,- (a) in sub-section s(1) and (2), for the words "make rules", the words "make rules, by notification in the Official Gazette," shall be substituted;
		(b) after sub-section (2), the following sub-section shall be inserted, namely:
		"(3) Every rule made by the State Government or a Board of Management of a Reformatory School under this Act shall be laid, as soon as may be after it is made, before the State Legislature."
13.	The Lepers Act, 1898 (3 of 1898)	Section 16 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature."
14.	The Indian Post Office Act, 1898 (6 of 1898)	In section 74, after sub-section (3), the following sub-section shall be inserted, namely:
		"(4) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
15.	The Live-stock Importation Act, 1898 (9 of 1898)	In section 4,- (a) in sub-section (1), for the words "State Government may make rules", the words "State Government may, by notification in the Official Gazette, make rules" shall be substituted;

Sl. No.	Short title	Amendments
		(b) after sub-section (1), the following sub-section shall be inserted, namely:
		"(1A) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
16.	The Indian Stamp Act, 1899 (2 of 1899)	In section 76, after sub-section (2), the following sub-section shall be inserted, namely:
		"(3) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
17.	The Glanders and Farcy Act,, 1899 (13 of 1899)	In section 14, after sub-section (3), the following sub-section shall be inserted, namely:
		"(3A) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
18.	The Ancient Monuments Preservation Act, 1904 (7 of 1904)	In section 23,- (a) in sub-section (1), for the words "may make rules", the words "may, by notification in the Official Gazette, make rules" shall be substituted;
		(b) after sub-section (2), the following sub-section shall be inserted, namely:
		"(3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
19.	The Dourine Act, 1910 (5 of 1910)	In section 14, after sub-section (3), the following sub-section shall be inserted, namely:
		"(3A) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
20.	The Banaras Hindu University Act, 1915 (16 of 1915)	In section 19, after sub-section (3), the following sub-sections shall be inserted, namely:
		"(4) Every Statute, Ordinance or Regulation made under this Act shall be published in the Official Gazette.
		(5) Every Statute; Ordinance or Regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the Statute, Ordinance or Regulation or both Houses agree that the Statute, Ordinance or Regulation should not be made, the Statute, Ordinance or Regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that Statute, Ordinance or Regulation.".

Sl. No.	Short title	Amendments
21.	The Inland Vessels Act, 1917 (1 of 1917)	In section 74, after sub-section (3), the following sub-section shall be inserted, namely:
		"(4) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
22.	The Aligarh Muslim University Act, 1920 (40 of 1920)	In section 31, after sub-section (3), the following sub-sections shall be inserted, namely:
		"(4) Every Statute, Ordinance or Regulation made under this Act shall be published in the Official Gazette.
		(5) Every Statute, Ordinance or Regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the Statute, Ordinance or Regulation or both Houses agree that the Statute, Ordinance or Regulation should not be made, the Statute, Ordinance or Regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that Statute, Ordinance or Regulation.".
23.	The Delhi University Act, 1922 (8 of 1922)	In section 32, after sub-section (3), the following sub-section shall be inserted, namely:
		"(4) Every Statute, Ordinance or Regulation made under this Act shall be published in the Official Gazette.
		(5) Every Statute, Ordinance or Regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive session aforesaid, both Houses agree in making any modification in the Statute, Ordinance or Regulation or both Houses agree that the statute, Ordinance or Regulation should not be made, the Statute, Ordinance or Regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that Statute, Ordinance or Regulation.".
24.	The Mussalman Wakf Act, 1923 (42 of 1923)	In section 11, after sub-section (2), the following sub-section shall be inserted, namely:
		"(3) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
25.	The Indian Forest Act, 1927 (16 of 1927)	In section 51,- (a) in sub-section (1), for the words "may make rules", the words "may, by notification in the Official Gazette, make rules" shall be substituted;

Sl. No.	Short title	Amendments
		(b) after sub-section (1), the following sub-section shall be inserted, namely:
		"(1A) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
26.	The Murshidabad Estate Administration Act, 1933 (23 of 1933)	In section 28,- (a) in sub-section (1), for the words "make rules", the words "and by notification in the Official Gazette, make rules" shall be substituted;
		(b) after sub-section (2), the following sub-section shall be added at the end, namely:
		"(3) Every rule made by the Board of Revenue under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
27.	The Sugar-cane Act, 1934 (15 of 1934)	Section 8 shall be re-numbered as sub-section (1), thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be added at the end, namely:
		"(2) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
28.	The Manoeuvres, Field Firing and Artillery Practice Act, 1938 (5 of 1938)	Section 13 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
29.	The War Injuries (Compensation Insurance) Act, 1943 (23 of 1943)	In section 20, after sub-section (2), the following sub-section shall be inserted, namely:
		"(3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
30.	The Minimum Wages Act, 1948 (11 of 1948)	Section 30A shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be inserted, namely:
		"(2) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
31.	The Reserve Bank (Transfer to Public Ownership) Act, 1948 (62 of 1948)	In section 6, after sub-section (2), the following sub-section shall be added at the end, namely:

Sl. No.	Short title	Amendments
		"(3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
32.	The Drugs (Control) Act, 1950 (26 of 1950)	In section 17,-
		(a) in sub-section (1), for the words "may make rules", the words "may, by notification in the Official Gazette, make rules" shall be substituted;
		(b) after sub-section (2), the following sub-section shall be inserted, namely:
		"(3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
33.	The Road Transport Corporations Act, 1950 (64 of 1950)	(a) In section 45, in sub-section (1), for the words "the State Government", the words "the State Government and by notification in the Official Gazette" shall be substituted;
		(b) after section 45, the following section shall be inserted, namely:
	Every rule and regulation to be laid before State Legislature.	"45A. Every rule and every regulation made under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
34.	The Jallianwala Bagh National Memorial Act, 1951 (25 of 1951)	In section 9, after sub-section (2), the following sub-section shall be inserted, namely:
		"(2A) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".

Sl. No.	Short title	Amendments
35.	The Visva-Bharati Act, 1951 (29 of 1951)	In section 31, after sub-section (3), the following sub-sections shall be inserted, namely:
		"(4) Every Statute, Ordinance or Regulation made under this Act shall be published in the Official Gazette.
		(5) Every Statute, Ordinance or Regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days, which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the Statute, Ordinance or Regulation or both Houses agree that the Statute, Ordinance or Regulation should not be made, the Statute, Ordinance or Regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that Statute, Ordinance or Regulation.".
36.	The Evancuee Interest (Separation) Act, 1951 (64 of 1951)	In section 23, after sub-section (2), the following sub-section shall be added at the end, namely:
		"(3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
37.	The Plantation Labour Act, 1951 (69 of 1951)	In section 43, after sub-section (3), the following sub-section shall be added at the end, namely:
		"(4) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
38.	The Salaries and Allowances of Officers of Parliament Act, 1953 (20 of 1953)	In section 11, for sub-section (2), the following sub-sections shall be substituted, namely:
		"(2) Every rule made by the Central Government under this Act shall be published in the Official Gazette.
		(3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each Houses of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive session aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".

Sl. No.	Short title	Amendments
39.	The Displaced Persons (Claims) Supplementary Act, 1954 (12 of 1954)	Section 12 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be added at the end, namely:
		"(2) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
40.	The Transfer of Evacuee Deposits Act, 1954 (15 of 1954)	In section 13, after sub-section (2), the following sub-section shall be added at the end, namely:
		"(3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
41.	The Delivery of Books and Newspapers (Public Libraries) Act, 1954 (27 of 1954)	Section 8 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-section shall be added at the end, namely:
		"(2) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
42.	The Prize Competitions Act, 1955 (42 of 1955)	In section 20, after sub-section (2), the following sub-section shall be added at the end, namely:
		"(3) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".

Sl. No.	Short title	Amendments
43.	The State Bank of Hyderabad Act, 1956 (79 of 1956)	In section 41, for sub-section (3), the following sub-section shall be substituted, namely:
		"(3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
44.	The Faridabad Development Corporation Act, 1956 (90 of 1956)	In section 36, for sub-section (3), the following sub-section shall be substituted, namely:
		"(3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
45.	The Indian Medical Council Act, 1956 (102 of 1956)	In section 32, for sub-section (2), the following sub-section shall be substituted, namely:
		"(2) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
46.	The Coal Bearing Areas (Acquisition and Development) Act, 1957 (20 of 1957)	In section 27, for sub-section (3), the following sub-section shall be substituted, namely:

Sl. No.	Short title	Amendments
		"(3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
47.	The Ancient Monuments and Archaeological Sites and Remains Act, 1958 (24 of 1958)	In section 38, for sub-section (4) the following sub-section shall be substituted, namely:
		"(4) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rules shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.".
48.	The Personal Injuries (Compensation Insurance) Act, 1963 (37 of 1963)	In section 24, for the marginal heading, the following marginal heading shall be substituted, namely: "Every scheme and rule to be laid before Parliament.".
49.	The Jawaharlal Nehru University Act, 1966 (53 of 1966)	Section 18 shall be re-numbered as sub-section (1), thereof, and after sub-section (1) as so re-numbered, the following sub-sections shall be inserted, namely:
		"(2) Every Statute, Ordinance or Regulation made under this Act shall be published in the Official Gazette.
		(3) Every Statute, Ordinance or Regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the Statute, Ordinance or Regulation or both Houses agree that the Statute, Ordinance or Regulation should not be made, the Statute, Ordinance or Regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that Statute, Ordinance or Regulation.".

Sl. No.	Short title	Amendments
50.	The Insecticides Act, 1968 (46 of 1968)	In section 37, after sub-section (2), the following sub-section shall be inserted, namely:
		"(3) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
51.	The Contact Labour (Regulation and Abolition) Act, 1970 (37 of 1970)	In section 35, after sub-section (3), the following sub-section shall be added at the end, namely:
		"(4) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
52.	The Medical Termination of Pregnancy Act, 1971 (34 of 1971)	In section 7, after sub-section (2), the following sub-section shall be inserted, namely:
		"(2A) Every regulation made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.".
53.	The North-Eastern Hill University Act, 1973 (24 of 1973)	Section 27 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-sections shall be inserted, namely:
		"(2) Every Statute, Ordinance or Regulation made under this Act shall be published in the Official Gazette.
		(3) Every Statute, Ordinance or Regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the Statute, Ordinance or Regulation or both Houses agree that the Statute, Ordinance or Regulation should not be made, the Statute, Ordinance or Regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that Statute, Ordinance or Regulation.".
54.	The University of Hyderabad Act, 1974 (39 of 1974)	Section 27 shall be re-numbered as sub-section (1) thereof, and after sub-section (1) as so re-numbered, the following sub-sections shall be inserted, namely:
		"(2) Every Statute, Ordinance or Regulation made under this Act shall be published in the Official Gazette.
		(3) Every Statute, Ordinance or Regulation made under this act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the Statute, Ordinance or Regulation or both Houses agree that the Statute, Ordinance or Regulation should not be made, the Statute, Ordinance or Regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that Statute, Ordinance or Regulation.".

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ಕೆ. ನೀಲಕಂಠಾಚಾರ್

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಅಧೀನ ಕಾರ್ಯದರ್ಶಿ (ಪ್ರಭಾರ),

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 102

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 100 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 12ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಸೆಪ್ಟೆಂಬರ್ 13ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ವಿಶೇಷ ಗೆಜೆಟ್‌ನ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(i)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ G.S.R.608(E) [No. F.No. 1/2/EM/2004] ದಿನಾಂಕ:13.09.2004ನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF FINANCE
(Department of Economic Affairs)
NOTIFICATION
New Delhi, the 13th September, 2004

G.S.R. 608(E): In exercise of the powers conferred by sub-section (1) and clause (a) of sub-section (2) of section 46 read with proviso to section 5 of the Foreign Exchange Management Act, 1999 (42 of 1999) and in consultation with the Reserve Bank, the Central Government, having considered it necessary in the public interest, hereby makes the following amendments in the Foreign Exchange Management (Current Account Transactions) Rules, 2000, namely:

I. (1) These rules may be called the Foreign Exchange Management (Current Account Transactions) (Amendment) Rules, 2004.

(2) They shall come into force from the date of their publication in the Official Gazette.

2. In the Foreign Exchange Management (Current Account Transactions) Rules, 2000, (a) in Schedule II,

(i) after item number 5 and the entries relating thereto, the following item number and the entries shall be inserted, namely:

"6. Remittance of hiring charges of transponders by	
(a) TV Channels	Ministry of Information and Broadcasting
(b) Internet service providers	Ministry of Communication and Information Technology";

(ii) Item number 10 and the entries relating thereto shall be omitted;

(b) In Schedule III,

(i) item number 1 and the entries relating thereto shall be omitted;

(ii) for item number 11 and the entries relating thereto, the following item number and the entries shall be substituted, namely:

"11. Commission, per transaction, to agents abroad for sale of residential flats or commercial plots in India exceeding USD 25,000 or 5% of the inward remittance whichever is more.";

(iii) Item numbers 12, 13 and 14 and the entries relating to each of items numbers shall be ommitted;

(iv) for item number 16 and the entries relating thereto, the following item numbers and the entries shall be substituted, namely:

"16. Remittance for purchase of trademark or franchise in India";

(v) item number 18 and the entries relating thereto shall be omitted.

[No. F1/2/EM/2004]

U.K. SINHA, Jt. Secy.

Note: The principal rules were published in the Gazette of India, Extraordinary Part-II, section 3(i) vide number G.S.R.381 (E), dated the 3rd May, 2000 and subsequently amended last vide G.S.R.731(E) dated the 5th September 2003.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 103

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 102 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 12ನೇ ಏಪ್ರಿಲ್, 2005

2004ನೇ ಸಾಲಿನ ಸೆಪ್ಟೆಂಬರ್ 6ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(i)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ G.S.R.570(E) [No. F.No.209/24/2003-CX-6] ದಿನಾಂಕ:06.09.2004ನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF FINANCE
(Department of Revenue)
NOTIFICATION
New Delhi, the 6th September, 2004
No.19/2004-CENTRAL EXCISE (N.T.)

G.S.R. 570(E): In exercise of the powers conferred by rule 18 of the Central Excise Rules, 2002 and in supersession of the Ministry of Finance, Department of Revenue, notification No. 40/2001-Central Excise (NT), dated the 26th June 2001, [G.S.R. 469(E), dated the 26th June, 2001] in so far as it relates to export to the countries other than Nepal and Bhutan, the Central Government hereby directs that there shall be granted rebate of the whole of the duty paid on all excisable goods falling under the First Schedule to the Central Excise Tariff Act, 1985 (5 of 1986), exported to any country other than Nepal and Bhutan, subject to the conditions, limitations and procedures specified hereinafter,-

(2) Conditions and limitatons:

(a) that the excisable goods shall be exported after payment of duty, directly from a factory or warehouse, except as otherwise permitted by the Central Board of Excise and Customs by a general or special order;

(b) the excisable goods shall be exported within six months from the date on which they were cleared for export from the factory of manufacture or warehouse or within such extended period as the Commissioner of Central Excise may in any particular case allow;

(c) that the excisable goods supplied as ship's stores for consumption on board a vessel bound for any foreign port are in such quantities as the Commissioner of Customs at the port of shipment may consider reasonable;

(d) the rebate claim by filing electronic declaration shall be allowed from such place of export and such date, as may be specified by the Board in this behalf;

(e) that the market price of the excisable goods at the time of exportation is not less than the amount of rebate of duty claimed;

(f) that the amount of rebate of duty admissible is not less than five hundred rupees;

(g) that the rebate of duty paid on those excisable goods, export of which is prohibited under any law for the time being in force, shall not be made.

(3) Procedures:

(a) Sealing of Goods and examination at the place of dispatch and export:

(i) The manufacturer exporters registered under the Central Excise Rules, 2002 and merchant-exporters who procure and export the goods directly from the factory or warehouse can exercise the option of exporting the goods sealed at the place of dispatch by a Central Excise Officer or under self-sealing;

(ii) Where the exporter desires self-sealing and self-certification, the manufacturer of the export goods or owner of the warehouse shall take the responsibility of sealing and certification;

(iii) The merchant-exporters other than those procuring the goods directly from the factory of warehouse shall export the goods sealed at the place of dispatch by a Central Excise Officer;

(iv) For the sealing of goods intended for export; at the place of dispatch, the exporter shall present the goods along with four copies of application in the Form ARE-I specified in the Annexure to this notification to the Superintendent or Inspector of Central Excise having jurisdiction over the factory of production or manufacture or warehouse;

(v) The said Superintendent or Inspector of Central Excise shall verify the identity of goods mentioned in the application and the particulars of the duty paid or payable, and if found in order, shall seal each package or the container in the manner as may be specified by the Commissioner of Central Excise and endorse each copy of the application in token of having such examination done;

(vi) The said Superintendent or Inspector of Central Excise shall return the original and duplicate copies of application to the exporter;

(vii) The triplicate copy of application shall be-

(a) sent to the officer with whom rebate claim is to be filed, either by post or by handing over to the exporter in a tamper proof sealed cover after posting the particulars in official records, or

(b) sent to the Excise Rebate Audit Section at the place of export in case rebate is to be claimed by electronic declaration on Electronic Data Inter-change system of customs;

(viii) The exporter may prepare quadruplicate copy of application for claiming any other export incentive. This copy shall be dealt in the same manner as the original copy of application;

(ix) Where goods are not exported directly from the factory of manufacture or warehouse, the triplicate copy of application shall be sent by the Superintendent having jurisdiction over the factory of manufacture or warehouse, who shall, after verification, forward the triplicate copy in the manner specified in sub-paragraph (vii);

(x) In case of export by parcel post after the goods intended for export have been sealed, the exporter shall affix to the duplicate application sufficient postage stamps to cover postal charges and shall present the documents, together with the package or packages to which it refers, to the postmaster at the office of booking;

(xi) Where the exporter desires self-sealing and self-certification for removal of goods from the factory or warehouse or any approved premises, the owner, the working partner, the Managing Director or the Company Secretary, of the manufacturing unit of the goods or the owner of warehouse or a person duly authorized by such owner, working partner or the Board of Directors of such Company, as the case may be, shall certify on all the copies of the application that the goods have been sealed in his presence, and shall send the original and duplicate copies of the application along with the goods at the place of export, and shall send the triplicate and quadruplicate copies of the application to the Superintendent or Inspector of Central Excise having jurisdiction over the factory or warehouse within twenty four hours of removal of the goods;

(xii) In case of self-sealing, the said Superintendent or Inspector of Central Excise shall, after verifying the particulars of the duty paid or duty payable and endorsing the correctness or otherwise, of these particulars-

(a) send to the officer with whom rebate claim is to be filed, either by post or by handing over to the exporter in a tamper proof sealed cover after posting the particulars in official records, or

(b) send to the Excise Rebate Audit Section at the place of export in case rebate is to be claimed by electronic declaration on Electronic Data Inter-change system of Customs;

(xiii) On arrival at the place of export, the goods shall be presented together with original duplicate and quadruplicate (optional) copies of the application to the Commissioner of Customs or other duly appointed officer;

(xiv) The Commissioner of Customs or other duly appointed officer shall examine the consignments with the particulars as cited in the application and if he finds that the same are correct and exportable in accordance with the laws for the time being in force, shall allow export thereof and certify on the copies of the application that the goods have been duly exported citing the shipping bill number and date and other particulars of export:

Provided that if the Superintendent or Inspector of Central Excise sealed packages or container at the place of dispatch, the officer of customs shall inspect the packages or container with reference to declarations in the application to satisfy himself about the exportability thereof and if the seals are found intact, he shall allow export.

(xv) The officer of customs shall return the original and quadruplicate (optional copy for exporter) copies of application to the exporter and forward the duplicate copy of application either by post or by post or by handing over to the exporter in a tamper proof sealed cover to the officer specified in the application, from whom the exporter wants to claim rebate:

Provided that where the exporter claims rebate by electronic declaration on the Electronic Data Inter-change system of Customs, the duplicate shall be sent to the Excise Rebate Audit Section at the place of export.

(xvi) The exporter shall use the quadruplicate copy for the purposes of claiming any other export incentive.

(b) Presentation of claim for rebate to Central Excise:

(i) Claim of the rebate of duty paid on all excisable goods shall be lodged along with original copy of the application to the Assistant Commissioner of Central Excise or the Deputy Commissioner of Central Excise having jurisdiction over the factory of manufacture or warehouse or, as the case may be, the Maritime Commissioner;

(ii) The Assistant Commissioner of Central Excise or the Deputy Commissioner of Central Excise of Central Excise having jurisdiction over the factory of manufacture or warehouse or, as the case may be, Maritime Commissioner of Central Excise shall compare the duplicate copy of application received from the officer of customs with the original copy received from the exporter and with the triplicate copy received from the Central Excise Officer and if satisfied that the claim is in order, he shall sanction the rebate either in whole or in part.

(c) Claim of rebate by electronic declaration: An exporter may enter the requisite information in the shipping bill filed at such place of export, as may be specified by the Board, for claiming rebate by electronic declaration on Electronic Data Inter-change system of Customs. The details of the corresponding application shall be entered in the Electronic Data Inter-change system of Customs upon arrival of the goods in the Customs area. After goods are exported or order under section 51 of the Customs Act, 1962 (52 of 1962) has been issued, the rebate of excise duty shall, if the claim is found in order, be sanctioned and disbursed by the Assistant Commissioner of Customs or the Deputy Commissioner of Customs.

(d) Special procedure for store for consumption on board an aircraft on foreign run: Notwithstanding anything contained in the above paragraphs, in case of mineral oil products falling under Chapter 27 of the First Schedule to the Central Excise Act, 1985 (5 of 1986) exported as stores for consumption on board an aircraft on foreign run, the rebate shall be granted for such quantity of the products as remain on board the aircraft after completion of an internal flight but prior to its reversion to foreign run. The concerned officer of Customs shall certify in the manner specified by the Commissioner of Central Excise the quantity of products left on board for determining the quantum of rebate.

(e) Cancellation of documents: If the excisable goods are not exported, the Assistant Commissioner of Central Excise or the Deputy Commissioner of Central Excise shall cancel the export documents.

Explanation I- "duty" for the purpose of this notification means duties of excise collected under the following enactments, namely:

(a) the Central Excise Act, 1944 (1 of 1944);
(b) the Additional Duties of Excise (Goods of Special Importance) Act, 1957 (58 of 1957);
(c) the Additional duties of Excise (Textiles and Textile Articles) Act, 1978 (40 of 1978);
(d) the National Calamity Contingent duty leviable under section 136 of the Finance Act, 2001 (14 of 2001), as amended by section 169 of the Finance Act, 2003 (32 of 2003) and further amended by section 3 of the Finance Act, 2004 (13 of 2004);
(e) special excise duty collected under a Finance Act;
(f) additional duty of excise as levied under section 157 of the Finance Act, 2003 (32 of 2003);
(g) Education Cess on excisable goods as levied under clause 81 read with clause 83 of the Finance (No.2) Bill, 2004.

Explanation II- For the purpose of this notification, the expression 'electronic declaration" means the declaration of the particulars relating to the export goods, lodged in the Customs Computer System, through the date-entry facility provided at the Service Center or the data communication networking facility provided by the Indian Customs and Central Excise Gateway (called ICEGATE), from the computer of the person authorized for this purpose.

Explanation III- For the purposes of this notification, "Maritime Commissioner" means the Commissioner of Central Excise under whose jurisdiction one or more of the port, airport, land customs station or post office of exportation, is located.

[F.No.209/24/2003-CX-6]

NEERAV KUMAR MALLICK, Under Secy.

Annexure
FORM A.R.E.1

Range.....................
Division...................Address........................ Original (White)/ Duplicate (Buff) Triplicate (Pink)/
Commissionerate...................... Quadruplicate (Green)

Application for removal of excisable goods for export by (Air/ Sea/ Post/ Land)*

To
Superintendent of Central Excise
............................(Full Postal Address)

1. Particulars of Assistant/ Deputy Commissioner of Central Excise/ Maritime Commissioner of Central Excise from whom rebate shall be claimed/ with whom bond/ undertaking is executed and his complete postal address.

2. I/ We.............of..............propose to export the under-mentioned consignment to...............(Country of destination) by Air/ Sea/ Land/ Parcel Post under claim for rebate/ bond/ undertaking*.

Particulars of Manufacturer of goods and his Central Excise Registration No	No.and description of packages	Gross weight/ Net weight	Marks and Nos. on packages	Quantity of goods	Description of goods	Value	Duty		No. and date of Invoice under which duty was paid/ No. and date of bond/ undertaking executed under rule 19	Amount of Rebate claimed	Remarks
							Rate	Amount (Rs.)			
1	2	3	4	5	6	7	8	9	10	11	12

3. I/ We hereby certify that the above-mentioned goods have been manufactured.
(a) availing facility/ without availing facility of CENVAT credit under CENVAT Credit Rules, 2002.
(b) availing facility/ without availing facility under Notification No.21/ 2004-Central Excise (N.T.), dated the 6th September, 2004 issued under rule 18 of Central Excise Rules, 2002.
(c) availing facility/ without availing facility under Notification No.43/2001-Central Excise (N.T.), dated the 26th June, 2001 issued under rule 19 of Central Excise (No.2) Rules, 2001.

4. I/ We hereby declare that the export is in discharge of the export obligation under a Quantity based Advance License/ Under Claim of Duty Drawback under Customs and Central Excise Duties Drawback Rules, 1995.

5. I/ We hereby declare that the above particulars are true and correctly stated.

Time of Removal.......................................

Signature of owner or his
Authorized agent with date.
Name in Block Letters and Designation (SEAL)

PART-A

Certification by Central Excise Officer

1. Certified that duty has been paid by debit entry in the Personal Ledger Account No........and/ or CENVAT Account Entry No............or recorded as payable in Daily Stock Account, on the goods described overleaf.

OR

Certified that the owner has entered into Bond No..........under Rule 19 of Central Excise Rules, 2002 with the..................[F.No.________________], duly accepted by the Assistant Commissioner/ Deputy Commissioner of Central Excise______________on____________(Date).

2. Certified that I have opened and examined the packages No.....................................and found that the particulars stated and the description of goods given overleaf and the packing list (if any) are correct and that all the packages have been stuffed in the container No.................with Marks.............and the same has been sealed with Central Excise Seal/ One Time Seal (OTS) No.............

3. I have verified with the records, the exporter is only availing the export incentives, as specified in box No.6 and found it to be true.

Certified that I have drawn three representative samples from the consignment (wherever necessary) and have handed over, two sets thereof duly sealed to the exporter/ his authorized representative.

Place.....................

Date.......................

Signature	Signature
(Name in Block Letters)	(Name in Block Letters)
Superintendent of Central Excise	Inspector of Central Excise

PART-B

CERTIFICATION BY THE OFFICER OF CUSTOMS

Certified that the consignment was shipped under my supervision under Shipping Bill No______ dated__________by S.S./ Flight No_______which left on the___________day of____________ (Months)____________(year)

OR

Certified that the above-mentioned consignment was stuffed in Container No.____________belonging to Shipping Line_____________based on the "Let Export Order" given on__________day of.___________(Month)__________(Year) on the Shipping Bill No.________dated______and sealed by seal/ one time lock No.__________in my supervision and the container was handed over to the Custodian M/s_____________for being shipped via__________________(Name of the Port).

OR

Certified that the above-mentioned consignment has been duly identified and has passed the land frontier today at___________in its original condition under Bill of Expoorts No._________Place_______Date__________.

Signature

(Name and designation of the Officer of Customs in Block Letters)/ (Seal)

PART-C

EXPORT BY POST

Certified that the consignment described overleaf has been dispatched by foreign post to_______________on_______________Day of 200______

Place_________

Date__________

Signature of Post Master with seal

PART-D

REBATE SANCTION ORDER

(On Original, Duplicate and Triplicate)

Refund Order No...................dated.........................Rebate of Rs..............(Rupees..................) sanctioned vide Cheque No.........................dated..................

Place....................

Date.....................

Assistant/ Deputy Commissioner/ Maritime
Commissioner of Central Excise

*Strike out inapplicable portions.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್.105

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 103 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 12ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಆಗಸ್ಟ್ 4ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(i)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ G.S.R.496(E) [No. F.No.13/9/2004/PRE] ದಿನಾಂಕ:04.08.2005ನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

LOK SABHA SECRETARIAT
NOTIFICATION
New Delhi, the 4th August, 2004

G.S.R. 496(E): On expiry of stipulated period of thirty days, while in session, after being laid on the Table of Lok Sabha, the following Rules take effect on 4th August, 2004 in terms of sub-section (4) of Section 75A of the Representation of People Act, 1951 and are hereby published for general information:

The Members of Lok Sabha (Declaration of Assets and Liabilities) Rules, 2004

1. Short title.-

These rules may be called the Members of Lok Sabha (Declaration of Assets and Liabilities) Rules,* 2004.

* Rules made by the Speaker, Lok Sabha in exercise of the powers conferred upon him by Sub-section (3) of Section 75A of the Representation of the People Act, 1951 (43 of 1951).

2. Definitions.-

In these rules the unless context otherwise requires:

(a) "Act" means the Representation of People Act, 1951 (43 of 1951);
(b) "Bulletin" means the Bulletin of the House of the People (Lok Sabha);
(c) "Committee" means the Committee of Privileges of the House of the People (Lok Sabha);
(d) "Form" means a form appended to these rules;
(e) "House" means the House of the People (Lok Sabha);
(f) "Member" means the an elected member of the House of the People (Lok Sabha);
(g) "Register" means the Register of Declaration of assets and liabilities of elected members maintained under Sub-rule (1) of Rule 4;
(h) "Secretary-General" means the Secretary-General of the House of the People (Lok Sabha) and includes any person for the time being performing the duties of the Secretary-General.
(i) "Section" means a Section of the Act;
(j) "Speaker" means the Speaker of the House of the People (Lok Sabha);
(k) words and expressions not defined herein but defined in the Act shall have the meanings respectively assigned to them in the Act.

3. Furnishing of information regarding assets and liabilities by members:

Every elected candidate for the House of the People shall, within ninety days from the date on which he makes and subscribes an oath or affirmation for taking his seat, furnish as in Form 1 the following information as required to be furnished by him to the Speaker in pursuance of sub-section (1) of Section 75A namely:

(i) the movable and immovable property of which he, his spouse and his dependant children are jointly or severally owners or beneficiaries;
(ii) his liabilities to may public financial institution; and
(iii) his liabilities to the Central Government or to the State Governments.

4. Register of declaration of assets and liabilities.-

(1) The Secretary-General shall maintain a register to be called the Register of Declaration of Assets and Liabilities of Elected Members as in Form II.
(2) The Secretary-General shall cause entries to be made in the Register based on the information furnished by every member under rule 3.
(3) The information in relation to each member, his spouse and dependant children shall be recorded on a separate page in the Register.
(4) The information contained in the Register shall be treated as confidential and it shall not be made available to any person except with the written permission of the Speaker.

5. References to be by complaints.-

(1) No reference of any question as to whether a member has wilfully contravened any provision of these rules shall be made except by a complaint in relation to such member made in accordance with the provisions of these rules.
(2) Every complaint referred to sub-rule (1) in relation to a member shall be made in writing to the Speaker by any other member or any citizen of India;

Provided that a complaint in relation to the Speaker shall be made to the Deputy Speaker and in that case these rules shall be applicable as if for the word "Speaker" the words "Deputy Speaker" were substituted.

(3) Before making any complaint in relation to any member, the complainant shall satisfy himself that there are reasonable grounds for believing that such member has wilfully contravened these rules.

(4) It shall be incumbent upon the complainant to ensure that the complaint is not false, frivolous or vexatious and it is made in good faith.

(5) Every Complaint made under rule 5-

(a) shall contain a concise statement of the material facts on which the complainant relies upon; and

(b) shall be accompanied by-

- (i) an affidavit duly affirmed by the complainant stating that the complaint is not false, frivolous or vexatious and that it is made in good faith; and
- (ii) copies of the documentary evidence, if any, on which the complainant relies upon and where the complainant relies on any information furnished to him by an person, a statement containing the names and addresses of such persons and the gist of such information as furnished by each such person.

(6) Every complaint shall be signed by the complainant and verified in the manner laid down in the Code of Civil Procedure, 1908 (5 of 1908), for the verification of pleadings.

(7) Every annexure to the complaint shall also be signed by the complainant and verified in the same manner as the complaint.

6. Procedure.-

(1) On receipt of a complaint under rule 5, the Speaker shall consider whether the complaint complies with the requirements of that rule.

(2) If the complaint does not comply with the requirements of rule 5, the speaker shall not entertain the complaint and intimate the complainant accordingly.

(3) If the complaint complies with the requirements of rule 5, the Speaker shall cause copies of the complaint and of the annexure thereto to be forwarded to the member in relation to whom the complaint has been made; and such member shall within fifteen days of receipt of such copies, or within such further period as the Speaker may for sufficient cause allow, forward his comments in writing thereon to the Speaker.

(4) After considering the comments, if any, in relation to the complaint, received under sub-rule (3) within the period allowed (whether originally or on extension under that sub-rule), the Speaker may-

- (a) if he is satisfied that there has not been any wilfull contravention of these rules, reject the complaint; or
- (b) if he is satisfied, having regard to the nature, and circumstances of the case that it is necessary or expedient so to do, refer the complaint to the Committee for making an inquiry and submitting a report to him.

(5) Where the Speaker makes a reference under sub-rule (4) to the Committee, he shall-

- (a) on receipt of the report from the Committee with a finding that there has not been any wilfull contravention of the provisions of these rules by the members, treat the matter as closed; or
- (b) on receipt of the report from the Committee with a finding that there has been a wilfull contravention of the provisions of these rules, cause the report of the Committee to be laid on the Table of the house without any delay for a decision by the House on the recommendation contained in the report of the Committee.

(6) The procedure which shall be followed by the Committee for the purpose of making an inquiry under sub-rule (4) shall be, so far as may be, the same as the procedure for inquiry and determination by the Committee of any question as to breach of privilege of the House by a member, and the Committee shall come to any finding that a member had wilfully contravened the provisions of these rules only after affording a reasonable opportunity to such member to represent his case and to be heard in person.

(7)_ Every decision referred to in sub-rules (4) and (5) shall be published in the Bulletin.

FORM-I

[See rule 3]

A. Information regarding assets & liabilities of members

1._ Name of the Member
(in block letters)
2. Father's/ Husband's Name
3. Permanent Address
4. Delhi Address
5. Party Affiliation
6. Date of Election
7. Date of taking oath/ making affirmation in the House

1. Details of immovable property

(1) Name of the State, District, Sub-division and Village in which property is situated.
(2) Details of property
  (a) House and buildings and their present value
  (b) Lands and their present value
(3) Whether held as owner or beneficiary
(4) Whether held jointly or severally.
If property held jointly with another person share of property held
(5) If not held in member's own name, state in whose name held and his/ her relationship with the member
(6) How acquired
(whether by purchase, lease, mortgage, inheritance, gifts or otherwise with date of acquisition and name of person from whom acquired)
(7) Any other relevant information which the member may like to mention

II. Details of movable property

(1) Description of the property (i.e. car/ motorcycle/ jewellery/ investments in banks/ stock markets/ companies/ financial institutions/ insurance policies etc.)
(2) Make, model (and also registration No. in case of vehicles) where necessary
(3) Mode of acquisition (purchase/ gift/ mortgage lease or otherwise)
(4) Purchase price of the property
(5) In case of purchase, source or sources from which financed
  (a) personal savings
  (b) other sources
(6) Any other relevant information which the member may like to furnish

III. Details of Liabilities of the member to public Financial Institutions/ Central Government and State Government

(1) Details of loans raised from Banks/ Companies/ Financial Institutions/ Central/ State Governments
(2) Amount of loans raised in each case
(3) The period for which these loans were raised in each case.

B. Information regarding immovable and movable properties held by member's spouse

1. Name of the Member's spouse (in block letters)
2. Father's/ Husband's Name
3. Permanent Address
4. Delhi Address

I. Details of immovable property

(1) Name of State, District, Sub-Division and Village in which property is situated.
(2) Details of property
  (a) House and building and their present value
  (b) Lands and their present value
(3) Whether held as owner or beneficiary
(4) Whether held jointly or severally. If property held jointly with member, share of property held

(5) If not held in spouse's own name, state in whose name held and his/ her relationship with the spouse.
(6) How acquired
(whether by purchase, lease, mortgage, inheritance, gift or otherwise with date of acquisition and name of person from whom acquired)
(7) Any other relevant information which the member may like to mention

II. Details of movable property

(1) Description of the property (i.e. car/ motorcycle/ jewellery/ investment in banks/ stock markets/ companies/ financial institutions/ insurance policies etc.
(2) Make, model (and also registration No. in case of vehicles) where necessary.
(3) Mode of acquisition (purchase/ gift/ mortgage lease or otherwise)
(4) Purchase price of the property.
(5) In case of purchase, source or sources from which financed.
  (a) personal savings
  (b) other sources
(6) Whether held as owner or beneficiary
(7) Whether held jointly or severally
(8) Any other relevant information which the member may like to furnish

C. Information regarding immovable and movable properties held by member's dependent children

1. Name of the member's dependent children (in block letters)
2. Father's/ Husband's name
3. Permanent Address
4. Delhi Address

I. Details of immovable property

(1) Name of State, District, Sub-divisional and Village in which property situated.
(2) Details of property
  (a) House and Buildings and their present value
  (b) Lands and their present value
(3) Whether held as owner or beneficiary
(4) Whether held jointly or severally, if property held jointly with member, share of property held
(5) If not held in the child's own name, state in whose name held and his/ her relationship with the child
(6) How acquired
(whether by purchase, lease, mortgage, inheritance, gift or otherwise with date of acquisition and name of person from whom acquired)
(7) Any other relevant information which the member may like to mention

II. Details of movable property

(1) Description of the property (i.e. car/ motorcycle/ jewellery/ investment in banks/ stock markets/ companies/ financial institutions/ insurance policies etc.)
(2) Make, model (and also registration No. in case of vehicles) where necessary
(3) Mode of acquisition
(purchase/ gift/ mortgage lease or otherwise)
(4) Purchase price of the property
(5) In case of purchase, source or sources from which financed
  (a) personal savings
  (b) other sources
(6) Whether held as owner or beneficiary
(7) Whether held jointly or severally
(8) Any other relevant information which the member may like to furnish

DECLARATION

I,....................................hereby declare that the information given above is true and correct to the best of my knowledge and belief.

In the event of any change in the information given above, I undertake to intimate the Speaker as provided under the rules.

Date:

Yours faithfully,
Signature/ thumb
impression of member

FORM-II
[See rule 4(1)]
PART-A

1. Name of the member (in block letters)
2. Father's/ husband's name
3. Permanent address
4. Delhi address
5. Details of immovable properties with value
6. Details of movable properties with value
7. Details of liabilities
8. Remarks

PART-B

1. Name of member's spouse (in block letters)
2. Permanent address
3. Delhi address
4. Details of immovable properties with value
5. Details of movable properties with value
6. Remarks

PART-C

1. Name of member's dependent children
2. Permanent address
3. Delhi address
4. Details of immovable properties with value
5. Details of movable properties with value
6. Remarks

[F.No.13/9/2004/PRE]
G.C. MALHOTRA, Secy.-General

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,
ರಿಚಾರ್ಡ್ ಲೋಬೋ
ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ
ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,
ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್.106

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 99 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 12ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಜನವರಿ 20ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.76(E) [No. NH-11014/7/2003-P&M] ದಿನಾಂಕ: 20.01.2005ನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF SHIPPING, ROAD TRANSPORT AND HIGHWAYS
(Department of Road Transport and Highways)
NOTIFICATION
New Delhi, the 20th January, 2005

S.O.76(E): In exercise of the powers conferred by sub-section (I) of section 3 of the Control of National Highways (Land and Traffic) Act, 2002 (13 of 2003), read with section 22 of the General Clauses Act, 1897 (10 of 1897), the Central Government hereby,-

(a) establishes the National Highways Administration mentioned in column 2 of the table given below in respect of the National Highways as specified in the corresponding column 4 of the said table to exercise the powers and discharge the functions conferred on it under the said Act; and

(b) defines the limits of the Highways as specified in corresponding column 3 of the said table within which or the length of the Highways as mentioned in the corresponding column 5 thereof on which the Highways administration as shown in the corresponding entry in column 2 shall have jurisdiction.

Table
(JURISDICTION)

Sl. No.	Highways Administration	Limits of the Highways defining jurisdiction of Highway Administration	National Highway (National Highway) Number	Length in km
1	2	3	4	5
	XX	XX	XX	XX
	State of Karnataka			
59.	Executive Engineer, National Highway Division, Bangalore.	Km. 216/94-324/50 on National Highway 4; Km. 0/0-91/00 on National Highway 206; Km. 265/80-468/40 on National Highway-209; and Km. 117/60-268/60 on National Highway 212.	National Highway-4 National Highway-206 National Highway-209 National Highway-212 **Total**	108 91 202 151 **552**
60.	Executive Engineer, National Highway Division, Mangalore	Km. 590/60-743/900 on National Highway-13; Km. 241/00-358, Km. 375.3-376.60 and Km.0/00-17/20 on National Highway-17; Km. 120/00-328, Km. 345-347.8 on National Highway-48; and Km. 91/00-153/00 on National Highway-206	National Highway-13 National Highway-17 National Highway-48 National Highway-206 **Total**	153 135 211 62 **561**
61.	Executive Engineer, National Highway Division, Chitradurga.	Km. 290/00-590/600 on National Highway-13; Km. 276/40-370/60, on National Highway-63; and Km. 153/00-229/60 on National Highway--206	National Highway-13 National Highway-63 National Highway-206 **Total**	301 95 146 **542**
62.	Executive Engineer, Special Division, Bangalore.	Km.28/30-120/00 on National Highway-48; Km.16/80-139/18 on National Highway-207	National Highway-48 National Highway-207 **Total**	92 122 **214**
63.	Executive Engineer, National Highway Division, Hubli	Km.0/00-84/12 on National Highway-4A;Km. 106/00-195/00 on National Highway-63; and Km. 50/00-193/40 on National Highway	National Highway-4A National Highway-63 National Highway-218 **Total**	84 89 143 **316**
64.	Executive Engineer, National Highway Division, Bijapur.	Km.348/75-423/70 on National Highway-9; Km. 30/34-290/00 on National Highway-13; Km. 195/00-268/00 on National Highway-63; and Km.0/00-50/00 on National Highway-218	National Highway-9 National Highway-13 National Highway-63 National Highway-218 **Total**	75 260 73 50 **458**
65.	Executive Engineer, National Highway Division, Karwar.	Km.93/70-241/00 on National Highway-17; Km. 0/00-106/00 on National Highway-63; and Km. 299/60-370/45 on National Highway-206	National Highway-17 National Highway-63 National Highway-206 **Total**	147 106 71 **324**
	XX	XX	XX	XX

2. This notification shall come in into force on the date on which the control of National Highways (Land and Traffic) Act, 2002 (13 of 2003) shall come into force.

[No. NH-11014/7/2003-P & M]

DHANENDRA KUMAR, Secy.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಪಿ.ಆರ್.107 ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 101 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 12ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಜನವರಿ 20ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(i)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ G.S.R.32(E) [No. F.No.X-11014/1/2003-DMS & PFA] ದಿನಾಂಕ: 20.01.2005ನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health)
NOTIFICATION
New Delhi, the 20th January, 2005

G.S.R. 32(E): Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by section 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, extraordinary, Part-II, section 3, sub-section (i), dated 28th August, 2003, under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number GSR 694(E), dated the 28th August, 2003, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on 28.08.2003;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government.

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to a mend the Drugs and Cosmetics Rules, 1945, namely:

1. (1) These rules may be called the Drugs and Cosmetics (IInd Amendment) Rules, 2005.
   (2) They shall come into force on the date of their publication in the Official Gazette.
   (3) In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as said rules),
   (1) in Part X-A, after rule 122-DA, the following shall be inserted, namely:
   122-DAA. Definition of Clinical trial.- For the purpose of this Part, "clinical trial" means a systematic study of new drugs(s) in human subjects(s) to generate data for discovering and/ or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and/ or adverse effects with the objective of determing safety and/ or efficacy of the new drug."
2. In the said rules for Schedule Y, the following Schedule shall be substituted, namely:

"SCHEDULE-Y

s[See rules 122A, 122B, 122D, 122DA, 122DAA and 122E]

REQUIREMENTS AND GUIDELINES FOR PERMISSION TO IMPORT AND/ OR MANUFACTURE OF NEW DRUGS FOR SALE OR TO UNDERTAKE CLINICAL TRIALS

1. Application for permission.- (1) Application for permission to import or manufacture new drugs for sale or to undertake clinical trials shall be made in Form 44 accompanied with following data in accordance with the appendices, namely:

(i) chemical and pharmaceutical information as prescribed in item 2 of Appendix I;
(ii) animal pharmacology data as prescribed in item 3 of appendix I and Appendix IV;

(a) specific pharmacological actions as prescribed in item 3.2 of Appendix I, and demonstrating, therapeutic potential for humans shalls be described according to the animal models and species used.
Wherever possible, dose-response relationships and ED 50s shall be submitted. Special studies conducted to elucidate mode of action shall also be described (Appendix IV);
(b) general pharmacological actions as prescribed in item 3.3 of Appendix I and item 1.2 of Appendix IV;
(c) pharmacokinetic data related to the absorption, distribution, metabolism and excretion of the test substance as prescribed in item 3.5 of Appendix I, Wherever possible, the drug effects shall be corelated to the plasma drug concentrations;

(iii) animal toxicology data as prescribed in item 4 of Appendix I and Appendix III;

(iv) human Clinical Pharmacology Data as prescribed in items 5,6 and 7 of Appendix I and as stated below:
(a) for new drug substances discovered in India, clinical trials are required to be carried out in India right from Phase I and data should be submitted as required under items 1, 2, 3, 4, 5 (data, if any, from other countries), and 9 of Appendix I;
(b) for new drug substances discovered in countries other than India, Phase I data as required under items 1, 2, 3, 4, 5 (data from other countries) and 9 of Appendix I should be submitted along with the application. After submission of Phase I data generated outside India to the Licensing Authority, permission may be granted to repeat Phase I trials and / or to conduct Phase II trials and subsequently Phase III trials concurrently with other global trials for that drug. Phase III trials are required to be conducted in India before permission to market the drug in India is granted;
(c) the data required will depend upon the purpose of the new drug application. The number of study subjects and sites to be involved in the conduct of clinical trial will depend upon the nature and objective of the study. Permission to carry out these trials shall generally be given in stages, considering the data emerging from earlier Phase(s);
(d) application for permission to initiate specific phase of clinical trial should also accompany Investigator's brochure, proposed protocal (Appendix X), case record form, study subject's informed consent document(s) (appendix V), investigator's undertaking (Appendix VII) and ethics committee clearance, if available, (Appendix VIII);
(e) reports of clinical studies submitted under items 5-8 of Appendix I should be in consonance with the format prescribed in Appendix II of this Schedule. The study report shall be certified by the Principal Investigator or, if no Principal Investigator is designated, then by each of the Investigators participating in the study. The certification should acknowledge the contents of the repot, the accurate presentation of the study as undertaken, and express agreement with the conclusions. Each page should be numbered;

(v) regulatory status in other countries as prescribed in item 9.2 of Appendix I, including Information in respect of restrictions imposed, if any, on the use of the drug in other countries, e.g. dosage limits, exclusion of certain age groups, warning about adverse drug reactions, etc. (item 9.2 of Appendix I). Likewise, if the drug has been withdrawn in any country by the manufacturer or by regulatory authorities, such information should also be furnished along with the reasons and their relevance, if any, to India. This information must continue to be submitted by the sponsor to the Licensing Authority during the course of marketing of the drug in India;

(vi) the full prescribing information should be submitted as part of the new drug application for marketing as prescribed in item 10 of Appendix I. The prescribing information (package insert) shall comprise the following sections; generic name; composition; dosage form/s, indications; dose and method of administration; use in special populations (such as pregnant women, lactating women, pediatric patients, geriatric patients etc.); contra-indications; warnings; precautions; drug interactions; undersirable effects; overdose; pharmacodynamic and pharmacokinetic properties; incompatibilities; shelf-life; packaging information, storage and handling instructions. All package inserts, promotional literature and patient education material subsequently produced are required to be consistent with the contents of the approved full prescribing information. The drafts of label and carton texts should comply with provisions of rules 96 and 97. After submission and approval by the Licensing Authority, no changes in the package insert shall be effected without such changes being approved by the Licensing Authority; and

(vii) complete testing protocol/s for quality control testing together with a complete impurity profile and release specifications for the product as prescribed in item 11 of Appendix I should be submitted as part of new drug application for marketing. Samples of the pure drug substance and finished product are to be submitted when desired by the regulatory authority.

(2) If the study drug is intended to be imported for the purposes of examination, test or analysis, the application for import of small quantities of drugs for such purpose should also be made in Form 12.

(3) For drugs indicated in life threatening/ serious diseases or diseases of special relevance to the Indian health scenario, the toxicological and clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate by the Licensing Authority.

2. CLINICAL TRIAL

(1) Approval for clinical trial

(i) Clinical trial on a new drug shall be initiated only after the permission has been granted by the Licensing Authority under rule 21(b), and the approval obtained from the respective ethics committee(s). The Licensing Authority as defined shall be informed of the approval of the respective institutional ethics committee(s) as prescribed in Appendix VIII. and the trial initiated at each respective site only after obtaining such an approval for that site. The trial site(s) may accept the approval granted to the protocol by the ethics committee of another trial site or the approval granted by an independent ethics committee (constituted as per Appendix VIII), provided that the approving ethics committee(s) is/ are willing to accept their responsibilities for the study at such trial site(s) and the trial site(s) is/ are willing to accept such an arrangement and that the protocol version is same at all trial sites.

(ii) All trial Investigator(s) should possess appropriate qualifications, training and experience and should have access to such investigational and treatment facilities as are relevant to the proposed trial protocol. A qualified physician (or dentist, when appropriate) who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions. Laboratories used for generating data for clinical trials should be compliant with Good Laboratory Practices. If services of a laboratory or a facilities outside the country are to be availed, its/ their name(s), address(s) and specific services to be used should be stated in the protocol to avail Licensing Authority's permission to send clinical trial related samples to such laboratory (ies) and/ or facility (ies). In all cases, information about laboratory (ies)/ facilities to be used for the trial, if other than those at the investigation site(s), should be furnished to the Licensing Authority prior to initiation of trial at such site(s).

(iii) Protocol amendments if become necessary before initiation or during the course of a clinical trial, all such amendments should be notified to the Licensing Authority in writing along with the approval by the ethics committee which has granted the approval for the study. NO deviations from or changes to the protocol should be implemented without prior written approval of the ethics committee and the Licensing Authority except when it is necessary to eliminate immediate hazards to the trial Subjects(s) or when change(s) involve(s) only logistic or administrative aspects of the trial. All such exceptions must be immediately notified to the ethics committee as well as to the Licensing Authority. Administrative and/ or logistic changes in the protocol should be notified to the Licensing Authority within 30 days.

(2) Responsibilities of Sponsor,-

(i) The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocal and Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Directorate General of Health services, Government of India as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.

(ii) Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity.

(iii) in case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report should be submitted within 3 months. The summary report should provide a brief description of the study, the number of patients exposed to the drug, dose and duration of exposure, details of adverse drug reactions (Appendix XI), if any, and the reason for discontinuation of the study or non-pursuit of the new drug application;

(iv) Any unexpected serious adverse event (SAE) (as defined in GCP Guidelines) occurring during a clinical trial should be communicated promptly (within 14 calendar days) by the Sponsor to the Licensing Authority and to the other investigator(s) participating in the study (see Appendix XI).

(3) Responsibilities of the Investigator(s),- The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigators(s) shall report all serious and unexpected adverse events to the Sponsor within 24 hours and to the Ethics Committee that accorded approval to the study protocol within 7 working days of their occurrence.

(4) Informed Consent,-

(i) In all trials, a freely given, informed, written consent is required to be obtained from each study subject. the Investigator must provide information about the study verbally as well as using a patient information sheet, in a language that is non-technical and understandable by the study subject. The Subject's consent must be obtained in writing using an 'Informed Consent Form'. Both the patient information sheet as well as the Informed Consent Form should have been approved by the ethics committee and furnished to the Licensing Authority. Any changes in the informed consent documents should be approved by the ethics committee and submitted to the Licensing Authority before such changes are implemented.

(ii) Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative (a legally acceptable representative is a person who is able to give consent for or authorize an intervention in the patient as provided by the law(s) of (India). If the Subject or his/ her legally acceptable representative is unable to read/ write-an impartial witness should be present during the entire informed consent process who must append his/her signatures to the consent form.

(iii) A checklist of essential elements to be included in the study subject's informed consent document as well as a format for the Informed Consent Form for study Subjects is given in Appendix V.

(5) Responsibilities of the Ethics Committee.-

(i) It is the responsibility of the ethics committee that reviews and accords its approval to a trial protocol to safeguard the rights, safety and well being of all trial subjects. The ethics committee should exercise particular care to protect the rights, safety and well being of all vulnerable subjects participating in the study, e.g., members of a group with hierarchical structure (e.g. prisoners, armed forces personnel, staff and students of medical, nursing and pharmacy academic institutions), patients with incurable diseases, unemployed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, minors or others incapable of personally giving consent. Ethics committee(s) should get document standard operating procedures' and should maintain a record of its proceedings.

(ii) Ethics Committee(s) should make, at appropriate intervals, an ongoing review of the trials for which they review the protocol(s). Such a review may be based on the periodic study progress reports furnished by the investigators and/ or monitoring and internal audit reports furnished by the Sponsor and/ or by visiting the study sites.

(iii) In case an ethics committee revokes its approval accorded to a trial protocol, it must record the reasons for doing so and at once communicate such a decision to the investigator as well as to the Licensing Authority.

(6) Human Pharmacology (Phase I).-

(i) The objective of studies in this Phase is the estimation of safety and tolerability with the initial administration of an investigational new drug into human(s). Studies in this Phase of development usually have non-therapeutic objectives and may be conducted in healthy volunteers subjects or certain types of patients. Drugs with significant potential toxicity e.g. cytotoxic drugs are usually studied in patients. Phase I trials should preferably be carried out by Investigators trained in clinical pharmacology with access to the necessary facilities to closely observe and monitor the Subjects.

(ii) Studies conducted in Phase I, usually intended to involve one or a combination of the following objectives:

(a) Maximum tolerated dose: To determine the tolerability of the dose range expected to be needed for later clinical studies and to determine the nature of adverse reactions that can be expected. These studies include both single and multiple dose administration.

(b) Pharmacokinetics, i.e., characterization of a drug's absorption, distribution, metabolism and excretion. Although these studies continue throughout the development plan, they should be performed to support formulation development and determine parhmacokinetic parameters in different age groups to support dosing recommendations.

(c) Pharmacodynamics: Depending on the drug and the endpoints studied, pharmacodynamic studies and studies relating to drug blood levels (pharmacokinetic/ pharmacodynamic studies) may be conducted in healthy volunteer Subjects or in patients with the target disease. If there are appropriate validated indicators of activity and potential efficacy, pharmacodynamic data obtained from patients may guide the dosage and dose regimen to be applied in later studies.

(d) Early Measurement of Drug Activity: Preliminary studies of activity or potential therapeutic benefit may be conducted in Phase I as a secondary objective. Such studies are generally performed in later Phases but may be appropriate when drug activity is readily measurable with a short duration of drug exposure in patients at this early stage.

(7) Therapeutic exploratory trials (Phase-II).-

(i) The primary objective of Phase II trials is to evaluate the effectiveness of a drug for a particular indication or indications in patients with the condition under study and to determine the common short-term side-effects and risks associated with the drug. Studies in Phase II should be conducted in a group of patients who are selected by relatively narrow criteria leading to a relatively homogeneous population. These studies should be closely monitored. An important goal for this Phase is to determine the dose(s) and regimen for Phase III trials. Doses used in Phase II are usually (but not always) less than the highest doses used in Phase I.

(ii) Additional objectives of Phase II studies can include evaluation of potential study endpoints, therapeutic regimens (including concomitant medications) and target populations (e.g. mild versus severe disease) for further studies in Phase II or III. These objectives may be served by exploratory analyses, examining subsets of data and by including multiple endpoints in trials.

(iii) If the application is for conduct of clinical trials as a part of multi-national clinical development of the drug, the number of sites and the patients as well as the justification for undertaking such trials in India shall be provided to the Licensing Authority.

(8) Therapeutic confirmatory trials (Phase III).-

(i) Phase III studies have primary objective of demonstration or confirmation of therapeutic benefit(s). Studies in Phase III are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication

and recipient population. These studies should be intended to provide an adequate basis for marketing approval. Studies in Phase III may also further explore the dose-response relationships (relationships among dose, drug concentration in blood and clinical response), use of the drug in wider populations, in different stages of disease, or the safety and efficacy of the drug in combination with other drug(s).

(ii) For drugs intended to be administered for long periods, trials involving extended exposure to the drug are ordinarily conducted in Phase III, although they may be initiated in Phase II. These studies carried out in Phase III complete the information needed to support adequate instructions for use of the drug (prescribing information).

(iii) For new drugs approved outside India, Phase III studies need to be carried out primarily to generate evidence of efficacy and safety of the drug in Indian patients when used as recommended in the prescribing information. Prior to conduct of Phase III studies in Indian subjects, Licensing Authority may require pharmacokinetic studies to be undertaken to verify that the data generated in Indian population is in conformity with the data already generated abroad.

(iv) If the application is for the conduct of clinical trials as a port of multi-national clinical development of the drug, the number of sites and patients as well as the justification for undertaking such trials in India should be provided to the Licensing Authority along with the application.

(9) Post Marketing Trials (Phase IV).-

Post Marketing trials are studies (other than routine surveillance) performed after drug approval and related to the approved indication(s). These trials go beyond the prior demonstration of the drug's safety, efficacy and dose definition. These trials may not be considered necessary at the time of new drug approval but may be required by the Licensing Authority for optimizing the drug's use. They may be of any type but should have valid scientific objectives. Phase IV trials include additional drug-drug interaction(s), dose-response or safety studies and trials designed to support use under the approved indication(s), e.g. mortality/ morbidity studies, epidemiological studies etc.

3. Studies in special populations:

Information supporting the use of the drug in children, pregnant women, nursing women, elderly patients, patients with renal or other organ systems failure, and those on specific concomitant medication is required to be submitted if relevant to the clinical profile of the drug and its anticipated usage pattern. Any claim sought to be made for the drug product that is not based on data submitted under preceding items of this Schedule should be supported by studies included under this item of the Schedule (Appendix I, item 8.3).

(1) Geriatrics.- Geriatric patients should be included in Phase III clinical trials (and in Phase II trials, at the Sponsor's option) in meaningful numbers, if-

(a) the disease intended to be treated is characteristically a disease of aging; or

(b) the population to be treated is known to include substantial numbers of geriatric patients; or

(c) when there is specific reason to expect that conditions common in the elderly are likely to be encountered; or

(d) when the new drug is likely to alter the geriatric patient's response (with regard to safety or efficacy) compared with that of the non geriatric patient.

(2) Pediatric.-

(i) The timing of pediatric studies in the new drug development program will depend on the medicinal product, the type of disease being treated, safety considerations, and the efficacy and safety of available treatments. For a drug expected to be used in children, evaluations should be made in the appropriate age group. When clinical development is to include studies in children, it is usually appropriate to begin with older children before extending the trial to younger children and then infants.

(ii) If the new drug is for diseases predominantly or exclusively affecting pediatric patients, clinical trial data should be generated in the pediatric population except for initial safety and tolerability data, which will usually be obtained in adults unless such initial safety studies in adults would yield little useful information or expose them to inappropriate risk.

(iii) If the new drug is intended to treat serious or life-threatening diseases, occurring in both adults and pediatric patients, for which there are currently no or limited therapeutic options, pediatric population should be included in the clinical trials early, following assessment of initial safety data and reasonable evidence of potential benefit. In circumstances where this is not possible, took of data should be justified in detail.

(iv) If the new drug has a potential for use in pediatric patients-pediatric studies should be conducted. These studies may be initiated at various phases of clinical development or after post marketing surveillance in adults if a safety concern exists. In cases where there is limited pediatric data at the time of submission of application-more data in pediatric patients would be expected after marketing authorization for use in children is granted.

(v) The pediatric studies should include-

(a) clinical trials,

(b) relative bioequivalence comparisons of the pediatric formulation with the adult formulation performed in adults, and

(c) definitive pharmacokinetic studies for dose selection across the age ranges of pediatric patients in whom the drug is likely to be used. These studies should be conducted in the pediatric patient population with the disease under study.

(vi) If the new drug is a major therapeutic advance for the pediatric population- the studies should begin early in the drug development, and this data should be submitted with the new drug application.

(vii) Pediatric Subjects are legally unable to provide written informed consent, and are dependent on their parents(s)/ legal guardian to assume responsibility for their participation in clinical studies. Written informed consent should be obtained from the parent/ legal guardian. However, all pediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand. Where appropriate, pediatric participants should additionally assent to enroll in the study. Mature minors and adolescents should personally sign and date a separately designed written assent form. Although a participant's wish to withdraw from a study must be respected, there may be circumstances in therapeutic studies for serious or life-threatening diseases in which, in the opinion of the Investigator and parent(s)/ legal guardian, the welfare of a pediatric patient would be jeopardized by his or her failing to participate in the study. In this situation, continued parental/ legal guardian consent should be sufficient to allow participation in the study.

(viii) For clinical trials conducted in the pediatric population, the reviewing ethics committee should include members who are knowledgeable about pediatric, ethical, clinical and psychosocial issues.

(3) Pregnant or nursing women.-

(i) Pregnant or nursing women should be included in clinical trials only when the drug is intended for use by pregnant/ nursing women or fetuses/ nursing infants and where the data generated from women who are not pregnant or nursing, is not suitable.

(ii) For new drugs intended for use during pregnancy, follow-up data (pertaining to a period appropriate for that drug) on the pregnancy, fetus and child will be required. Where applicable, excretion of the drug or its metabolites into human milk should be examined and the infant should be monitored for predicted pharmacological effects of the drug.

(2) Post Marketing Surveillance.-

(i) Subsequent to approval of the product, new drugs should be closely monitored for their clinical safety once they are marketed. The applicants shall furnish Periodic Safety Update Reports (PSURs) in order to-

(a) report all the relevant new information from appropriate sources;

(b) relate these data to patient exposure;

(c) summarize the market authorization status in different countries and any significant variations related to safety; and

(d) indicate whether changes should be made to product information in order to optimize the use of the product.

(ii) Ordinarily all dosage forms and formulations as well as indications for new drugs should be covered in one PSUR. Within the single PSUR separate presentations of data for different dosage forms, indications or separate population need to be given.

(iii) All relevant clinical and non-clinical safety data should cover only the period of the report (interval data). The PSURs shall be submitted every six months for the first two years after approval of the drug is granted to the applicant. For subsequent two years-the PSURs need to be submitted annually. Licensing authority may extend the total duration of submission of PSURs if it is considered necessary in the interest of public health. PSURs due for a period must be submitted within 30 calendar days of the last day of the reporting period. However, all cases involving serious unexpected adverse reactions must be reported to the licensing authority within 15 days of initial receipt of the information by the applicant. If marketing of the new drug is delayed by the applicant after obtaining approval to market, such data will have to be provided on the deferred basis beginning from the time the new drug is marketed.

(iv) New studies specifically planned or conducted to examine a safety issue should be described in the PSURs.

(v) **A PSUR Should be structured as follows:**

(a) A title page stating: Periodic safety update report for the product, applicant's name, period covered by the report, date of approval of new drug, date of marketing of new drug and date of reporting:
(b) Introduction,
(c) Current worldwide market authorization status,
(d) Update of actions taken for safety reasons,
(e) Changes to reference safety information,
(f) Estimated patient exposure,
(g) Presentation of individual case histories,
(h) Studies,
(i) Other information,
(j) Overall safety evaluation,
(k) Conclusion,
(l) Appendix providing material relating to indications, dosing, pharmacology and other related information.

(5) Special studies: Bioavallability/ Bioequivalence Studies.-

(i) For drugs approved elsewhere in the world and absorbed systemically, bioequivalence with the reference formulation should be carried out wherever applicable. These studies should be conducted under the labeled conditions of administration. Data on the extent of systemic absorption may be required for formulations other than those designed for systemic absorption.

(ii) Evaluation of the effect of food on absorption following oral administration should be carried out. Data from dissolution studies should also be submitted for all solid oral dosage forms.

(iii) Dissolution and bioavailability data submitted with the new drug application must provide information that assures bioequivalence or establishes bioavailability and dosage correlations between the formulation(s) sought to be marketed and those used for clinical trials during clinical development of the product. (See items 8.1, 8.2 and 8.3 of Appendix I,).

(iv) All bioavailability and bioequivalence studies should be conducted according to the Guidelines for Bioavailability and Bioequivance studies as prescribed.

Note: The data requirements stated in this Schedule are expected to provide adequate information to evaluate the efficacy, safety and therapeutic rationale of new drugs (as defined under rule 122-e) prior to the permission for sale. Depending upon the nature of new drugs and disease(s), additional information may be required by the Licensing Authority. The applicant shall certify the authencity of the data and documents submitted in support of an application for new drug. The Licensing Authority reserves the right to reject any data or any document(s) if such data or contents of such documents are found to be of doubtful integrity.

APPENDIX-I

DATA TO BE SUBMITTED ALONG WITH THE APPLICATION TO CONDUCT CLINICAL TRIALS/ IMPORT/ MANUFACTURE OF NEW DRUGS FOR MARKETING IN THE COUNTRY

1. Introduction
   A brief description of the drug and the therapeutic class to which it belongs.
2. Chemical and pharmaceutical information
   2.1. Information on active ingredients
   Drug information (Generic Name, Chemical Name or INN)
   2.2 Physicochemical Data
   a. Chemical name and Structure
   Empirical formula
   Molecular weight
   b. Physical properties
   Description
   Solubility
   Rotation
   Partition coefficient
   Dissociation constant
   2.3 Analytical Data
   Elemental analysis
   Mass spectrum
   NMR spectra
   IR spectra
   UV spectra
   Polymorphic identification
   2.4 Complete monograph specification including
   Identification
   Identity/ quantification of impurities
   Enantiomeric purity
   Assay
   2.5. Validations
   Assay method
   Impurity estimation method
   Residual solvent/ other volatile impurities (OVI) estimation method
   2.6 Stability Studies (for details refer Appendix IX)
   Final release specification
   Reference standard characterization
   Material safety data sheet
   2.7 Data on Formulation
   Dosage form
   Composition
   Master manufacturing formula
   Details of the formulation (including inactive ingredients)
   In process quality control check
   Finished product specification
   Excipient compatibility study
   Validation of the analytical method
   Comparative evaluation with international brands(s) or approved Indian brands, if applicable
   Pack presentation
   Dissolution
   Assay
   Impurities
   Content uniformity
   pH
   Force degradation study

Stability evaluation in market intended pack at proposed storage conditions
Packing specifications
Process validation

When the application is for clinical trials only, the international non-proprietary name (INN) or generic name, drug category, dosage form and data supporting stability in the intended container-closure system for the duration of the clinical trial (information covered in item Nos.2.1, 2.3, 2.6, 2.7) are required.

3. Animal Pharmacology (for details refer Appendix IV)
   3.1 Summary
   3.2 Specific pharmacological actions
   3.3 General pharmacological actions
   3.4 Follow-up and Supplemental Safety Pharmacology Studies
   3.5 Pharmacokinetics: absorption, distribution; metabolism; excretion
4. Animal Toxicology (for details refer Appendix III)
   4.1 General Aspects
   4.2 Systemic Toxicity Studies
   4.3 Male Fertility Study
   4.4 Female Reproduction and Developmental Toxicity Studies
   4.5 Local toxicity
   4.6 Allergenicity/ Hypersensitivity
   4.7 Genotoxicity
   4.8 Carcinogenicity
5. Human / Clinical pharmacology (Phase I)
   5.1 Summary
   5.2 Specific Pharmacological effects
   5.3 General Pharmacological effects
   5.4 Pharmacokinetics, absorption, distribution, metabolism, excretion
   5.5 Pharmacodynamics / early measurement of drug activity
6. Therapeutic exploratory trials (Phase II)
   6.1 Summary
   6.2 Study reports(s) as given in Appendix II
7. Therapeutic confirmatory trials (Phase III)
   7.1 Summary
   7.2 Individual study reports with listing of sites and Investigators.
8. Special studies
   8.1 Summary
   8.2 Bio-availability/ Bio-equivalence.
   8.3 Other studies e.g. geriatrics, paediatrics, pregnant or nursing women
9. Regulatory status in other countries
   9.1 Countries where the drug is
   a. Marketed
   b. Approved
   c. Approved as IND
   d. Withdrawn, if any, with reasons
   9.2 Restrictions on use, if any, in countries where marketed/ approved
   9.3 Free sale certificate or certificate of analysis, as appropriate.
10. Prescribing information
   10.1 Proposed full prescribing information
   10.2 Drafts of labels and cartons
11. Samples and Testing Protocol/s
   11.1 Samples of pure drug substance and finished product (an equivalent of 50 clinical doses, or more number of clinical doses if prescribed by the Licensing Authority), with testing protocol/s, full impurity profile and release specifications.

NOTES:

(1) All items may not be applicable to all drugs. For explanation, refer text of Schedule Y.

(2) For requirements of data to be submitted with application for clinical trials refer text of this Schedule.

APPENDIX I-A

DATA REQUIRED TO BE SUBMITTED BY AN APPLICANT FOR GRANT OF PERMISSION TO IMPORT AND/ OR MANUFACTURE A NEW DRUG ALREADY APPROVED IN THE COUNTRY

1. Introduction
   A brief description of the drug and the therapeutic class
2. Chemical and pharmaceutical information
   2.1 Chemical name, code name or number, if any; non-proprietary or generic name, if any, structure; physico-chemical properties
   2.2 Dosage form and its composition
   2.3 Test specifications
       (a) active ingredients
       (b) inactive ingredients
   2.4 Tests for identification of the active ingredients and method of its assay
   2.5 Outline of the method of manufacture of active ingredients
   2.6 Stability data
3. Marketing information
   3.1 Proposed package insert/ promotional literature
   3.2 Draft specimen of the label and carton
4. Special studies conducted with approval of Licensing Authority
   4.1 Bioavailability/ Bioequivalence and comparative dissolution studies for oral dosage forms
   4.2 Sub-acute animal toxicity studies for intravenous infusions and injectables

APPENDIX-II

STRUCTURE, CONTENTS AND FORMAT FOR CLINICAL STUDY REPORTS

1. Title Page:-
   This page should contain information about the title of the study, the protocol code, name of the investigational product tested, development Phase, indication studied, a brief description of the trial design, the start and end date of patent accrual and the names of the Sponsor and the participating Institutes (Investigators).
2. Study Synopsis (1 to 2 pages): A brief overview of the study from the protocol development to the trial closure should be given here. This section will only summarize the important conclusions derived from the study.
3. Statement of compliance with the 'Guidelines for Clinical Trials on Pharmaceutical Products in India-GCP Guidelines' issued by the Central Drugs Standard Control Organization, Ministry of Health, Government of India.
4. List of Abbreviations and Definitions
5. Table of contents
6. Ethics Committee:
7. This section should document that the study was conducted in accordance with the ethical principles of Declaration of Helsinki. A detailed description of the Ethics Committee constitution and date(s) of approvals of trial documents for each of the participating sites should be provided. A declaration should state that EC notifications as per Good Clinical Practice Guidelines issued by Central Drugs Standard Control Organization and Ethical Guidelines for Biomedical Research on Human Subjects, issued by Indian Council of Medical Research have been followed.
8. Study Team:
   Briefly describe the administrative structure of the study (Investigators, site staff, Sponsor/ designates, Central laboratory etc.)
9. Introduction:
   A brief description of the product development rationale should be given here.
   Study Objective:
   A statement describing the overall purpose of the study and the primary and secondary objectives to be achieved should be mentioned here.
10. Investigational Plan:

This section should describe the overall trial design, the Subject selection criteria, the treatment procedures, blinding/ randomization techniques if any, allowed/ disallowed concomitant treatment, the efficacy and safety criteria assessed, the data quality assurance procedures and the statistical methods planned for the analysis of the data obtained.

11. Trial Subjects
A clear accounting of all trial Subjects who entered the study will be given here. Mention should also be made of all cases that were dropouts or protocol deviations. Enumerate the patients screened, randomised, and prematurely discontinued State Reasons for premature discontinuation of therapy in each applicable case.

12. Efficacy evaluation
The results of evaluation of the efficacy variables will be described in this section with appropriate tabular and graphical representation. A brief description of the demographic characteristics of the trial patients should also be provided along with a listing of patients and observations excluded from efficacy analysis.

13. Safety Evaluation
This section should include the complete list
13.1 all serious adverse events, whether expected or unexpected and
13.2 unexpected adverse events whether serious or not (compliled from data received as per Appendix XI).
The comparison of adverse events across study groups may be presented in a tabular or graphical form. This section should also give a brief narrative of all important events considered related to the investigational product.

14. Discussion and overall Conclusion
Discussion of the important conclusions derived from the trial and scope for further development.

15. List of References

16. Appendices
List of Appendices to the Clinical Trial Report
a. Protocol and amendments
b. Specimen of Case Record Form
c. Investigators' name(s) with contact addresses, phone, email etc.
d. Patient data listings
e. List of trial participants treated with investigational product
f. Discontinued participants
g. Protocol deviations
h. CRFs of cases involving death and life threatening adverse event cases
i. Publications from the trial
j. Important publications referenced in the study
k. Audit certificate, if available
l. Investigator's certificate that he/ she has read the report and that the report accurately describes the conduct and the results of the study.

APPENDIX-III
ANIMAL TOXICOLOGY (NON-CLINICAL TOXICITY STUDIES)

General Principles

Toxicity studies should comply with the norms of Good Laboratory Practice (GLP). Briefly, these studies should be performed by suitably trained and qualified staff employing properly calibrated and standardized equipment of adequate size and capacity. Studies should be done as per written protocols with modifications (if any) verifiable retrospectively. Standard operating procedures (SOPs) should be followed for all managerial and laboratory tasks related to these studies. Test substances and test systems (in-vitro or in-vivo) should be properly characterized and standardized. All documents belonging to each study, including its approved protocol, raw data, draft report, final report, and histology slides and paraffin tissue blocks should be preserved for a minimum of 5 years after marketing of the drug.

Toxicokinetic studies (generation of pharmacokinetic data either as an integral component of the conduct of non-clinical toxicity studies or in specially designed studies) should be conducted to assess the systemic exposure achieved in animals and its relationship to dose level and the time course of the toxicity

study. Other objectives of toxicokinetic stuides include obtaining data to relate the exposure achieved in toxicity studies to toxicological findings and contribute to the assessment of the relevance of these findings to clinical safety, to support the choice of species and treatment regimen in nonclinical toxicity studdies and to provide information which, in conjuction with the toxicity findings, contributes to the design of subsequent non-clinical toxicity studies.

1.1 Systemic Toxicity Studies

1.1.1 Single-dose Toxicity Studies: These studies (see Appendix I item 4.2) should be carried out in 2 rodent species (mice and rats) using the same route as intended for humans. In addition, unless the intended route of administration in humans is only intravenous, at least one more route should be used in one of the species to ensure systemic absorption of the drug. This route should depend on the nature of the drug. A limit of 2g/kg (or 10 times the normal dose that is intended in humans, whichever is higher) is recommended for oral dosing. Animals should be observed for 14 days after the drug administration, and minimum lethal dose (MLD) and maximum tolerated dose (MTD) should be established. If possible, the target organ of toxicity should also be determined. Mortality should be observed for up to 7 days after parenteral administration and up to 14 days after oral administration. Symptoms, signs and mode of death should be reported, with appropriate macroscopic and microscopic findings where necessary. LD_{10} and LD_{50} should be reported preferably with 95 percent confidence limits. If LD_{50}s cannot be determined, reasons for the same should be stated.

The dose causing severe toxic manifestations or death should be defined in the case of cytotoxic anticancer agents, and the post-dosing observation period should be to 14 days. Mice should first be used for determination of MTD. Findings should then be confirmed in rat for establishing linear relationship between toxicity and body surface area. In case of nonlinerarity, data of the more sensitive species should be used to determine the Phase I starting dose. Where rodents are known to be poor predictors of human toxicity (e.g., antifolates), or where the cytotoxic drug acts by a novel mechanism of action, MTD should be established in non-rodent species.

1.1.2 Repeated-dose Systemic Toxicity Studies: These studies (see Appendix I, item 4.2) should be carried out in at least two mammalian species, of which one should be a non-rodent. Dose ranging studies should precede the 14-, 28-, 90- or 180- day toxicity studies. Duration of the final systemic toxicity study will depend on the duration, therapeutic indication and scale of the proposed clinical trial. (see Item 1.8). If a species is known to metabolize the drug in the same way as humans, it should be preferred for toxicity studies.

In repeated-dose toxicity studies the drug should be administered 7 days a week by the route intended for clinical use. The number of animals required for these studies, i.e. the minimum number of animals on which data should be available, is shown in Item 1.9.

Wherever applicable, a control group of animals given the vehicle alone should be included, and three other groups should be given graded doses of the drug. The highest dose should produce observable toxicity; the lowest dose should not cause observable toxicity, but should be comparable to the intended therapeutic dose in humans or a multiple of it. To make allowance for the sensitivity of the species the intermediate dose should cause some symptoms, but not gross toxicity or death, and should be placed logarithmically between the other two doses.

The parameters to be monitored and recorded in long-term toxicity studies should include behavioral, physiological, biochemical and microscopic observations. In case of parenteral drug administration, the sites of injection should be subjected to gross and microscopic examination. Initial and final electrocardiogram and fundus exmination should be carried out in the non-rodent species.

In the case of cytotoxic anticancer agents dosing and study design should be in accordance with the proposed clinical schedule in terms of days of exposure and number of cycles. Two rodent species may be tested for initiating Phase I trials. A non-rodent species should be added if the drug has a novel mechanism of action, or if permission for Phase II, III or marketing is being sought.

For most compounds, it is expected that single dose tissue distribution studies with sufficient sensitivity and specificity will provide an adequate assessment of tissue distribution and the potential for accumulation. Thus, repeated dose tissue distribution studies should not be required uniformly for all compounds and should only be conducted when appropriate data cannot be derived from other sources. Repeated dose studies may be appropriate under certin circumstances based on the data from single dose tissue distribution studies, toxicity and toxicokinetic studies. The studies may be most appropriate for compounds which have an apparently long half life, incomplete elimination or unanticipated organ toxicity.

Notes:

(i) Single Dose Toxicity Study: Each group should contain at least 5 animals of either sex. At least four graded doses should be given. Animals should be exposed to the test substance in a single bolus or by continous infusion or several doses within 24 hours. Animals should be observed for 14 days Single of intoxication, effect on body weight, gross pathological changes should be reported. It is desirable to include histo-pathology of grossly affected organs, if any.

(ii) Dose-ranging Study: Objectives of this study include the identification of target organ of toxicity and establishment of MTD for subsequent studies.

(a) Rodents: Study should be performed in one rodent species (preferably rat) by the proposed clinical route of administration. At least four graded doses including control should be given, and each dose group as well as the vehicle control should consist of a minimum of 5 animals of each sex. Animal should be exposed to the test substance daily for 10 consecutive days. Highest dose should be the maximum tolerated dose of single-dose study. Animals should be observed daily for signs of intoxication (general appearance, activity and behaviour etc), and periodically for the body weight and laboratory parameters. Gross examination of viscera and microscopic examination of affected organs should be done.

(b) Non-rodents: One male and one female are to be taken for ascending Phase MTD study. Dosing should start after initial recording of cage-side and laboratory parameters. Starting dose may be 3 to 5 times the extrapolated effective dose or MTD (whichever is less), and dose excalation in suitable steps should be done every third day after drawing the samples for laboratory parameters. Dose should be lowered appropriately when clinical or laboratory evidence of toxicity are observed. Administration of test substance should then continue for 10 days at the well-tolerated dose level following which, samples for laboratory parameters should be taken. Sacrifice, autopsy and microscopic examination of affected tissues should be performed as in the case of rodents.

(iii) 14-28 Day repeated-dose toxicity studies: One rodent (6-10/ sex/ group) and one non-rodent (2-3/ sex/group) species are needed. Daily dosing by proposed clinical route at three dose levels should be done with highest dose having observable toxicity, mid-dose between high and low dose, and low dose. The doses should preferably be multiples of the effective dose and free from toxicity. Observation parameters should include cage-side observations, body weight changes, food/water intake, blood biochemistry, haematology, and gross and microscopic studies of all viscera and tissues.

(iv) 90-Day repeated-dose toxicity studies: One rodent (15-30/sex/ group) and one non-rodent (4-6/sex/group) species are needed. Daily dosing by proposed clinical route at three graded dose levels should be done. In addition to the control a "high-dose-reversal" group and its control group should be also included. Parameters should include sings of intoxication (general appearance, activity and behavior etc), body weight, food intake, blood biochemical parameters, hematological values, urine analysis, organ weights, gross and microscopic study of viscera and tissues. Half the animals in "reversal" groups (treated and control/ should be sacrificed after 14 days of stopping the treatment. The remaining animals should be sacrificed after 28 days of stopping the treatment or after the recovery of signs and/ or clinical pathological changes-whichever comes later, and evaluated for the paramenters used for the main study.

(v) 180-Day repeated-dose toxiciy studies: One rodent (15-30/sex/ group) and one non-rodent (4-6/sex/group) species are needed. At least 4 groups, including control, should

be taken. Daily dosing by proposed clinical route at three graded dose levels should be done. Parameters should include signs of intoxication, body Wight, food intake, blood biochemistry, hematology, urine analysis, organ weights, gross and microscopic examination of organs and tissues.

1.2 Male Fertility Study

One rodent species (preferably rat) should be used. Dose selection should be done from the results of the previous 14 or 28-day toxicity study in rat. Three dose groups, the highest one showing minimal toxicity in systemic studies, and a control group should be taken. Each group should consist of 6 adult male animals. Animals should be treated with the test substance by the intended route of clinical use for minimum 28 days and maximum 70 days before they are paired with female animals of proven fertility in a ratio of 1:2 for mating.

Drug treatment of the male animals should continue during pairing. Pairing should be continued till the detection of vaginal plug or 10 days, whichever is earlier. Females getting thus pregnant should be examined for their fertility index after day 13 of gestation. All the male animals should be sacrificed at the end of the study. Weights of each testis and epididymis should be separately recorded. Sperms from one epidiymis should be examined for their motility and morphology. The other epididymis and both testes should be examined for their histology.

1.3 Female Reproduction and Developmental Toxicity Studies

These studies (see Appendix I, item 4.4) need to be carried out for all drugs proposed to be studied or used in women of child bearing age. Segment I, II and III studies (see below) are to be performed in albino mice or rats, and segment II study should include albino rabbits also as a second test species.

On the occasion, when the test article is not compatible with the rabbit (e.g. antibiotics which are effective against gram positive, anaerobic organisms and protozoas) the Segment II data in the mouse may be substituted.

1.3.1 Female Fertility Study (Segment I): The study should be done in one rodent species (rat preferred). The drug should be administered to both males and females, beginning a sufficient number of days (28 days in males and 14 days in females) before mating. Drug treatment should continue during mating and, subsequently, during the gestation period. Three graded doses should be used, the highest dose (usually the MTD obtained from previous systemic toxicity studies) should not affect general health of the parent animals. At least 15 males and 15 females should be used per dose group. Control and the treated groups should be of similar size. The route of administration should be the same as intended for therapeutic use.

Dams should be allowed to litter and their medication should be continued till the weaning of pups. Observations on body weight, food intake, clinical signs of intoxication, mating behaviour, progress of gestation/ parturition periods, length of gestation, parturition, post-partum health and gross pathology (and histopathology of affected organs) of dams should be recorded. The pups from both treated and control groups should be observed for general signs of intoxication, sex-wise distribution in different treatment groups, body weight, growth parameters, survival, gross examination, and autopsy. Histopathology of affected organs should be done.

1.3.2 Teratogenicity Study (Segment II): One rodent (preferably rat) and one non-rodent (rabbit) species are to be used. The drug should be administered throughout the period of organogenesis, using three dose levels as described for segment I. The highest dose should cause minimum maternal toxicity and the lowest one should be proportional to the proposed dose for clinical use in humans or a multiple of it. The route of administration should be the same as intended for human therapeutic use.

The control and the treated groups should consist of at least 20 pregnant rats (or mice) and 12 rabbits, on each dose level. All foetuses should to be subjected to gross examination, one of the foetuses should be examined for skeletal abnormalities and the other half for visceral abnormalities. Observation parameters should include: (Dams) signs of intoxication, effect on body weight, effect on food intake, examination of uterus,

ovaries and uterine contents, number of corpora lutea, implanatation sites, resorptions (if any); and for the foetuses, the total number, gender, body length, weight and gross/ visceral/ skeletal abnormalities, if any.

1.3.3 Perinatal Study (Segment III): This study is specially recommended if the drug is to be given to pregnant or nursing mothers for long periods or where there are indications of possible adverse effects on foetal development. One rodent species (preferably rat) is needed. Dosing at levels comparable to multiples of human dose should be done by the intended clinical route. At least 4 groups (including control), each consisting of 15 dams should be used. The drug should be administered throughout the last trimester of pregnancy (from day 15 of gestation) and then the dose that couases low foetal loss should be continued throughout lactation and weaning. Dams should then be sacrificed and examined as described below.

One male and one female from each litter of F_1 generation (total 15 males and 15 females in each group) should be selected at waning and treated with vehicle or test substance (at the dose levels described above) throughout their periods of growth to sexual maturity, pairing, gestation, parturition and lactation. Mating performance and fertility of F_1 generation should thus be evaluated to obtain the F_2 generation whose growth paramenters should be monitored till weaning. The criteria of evaluation should be the same as described earlier (3.4.1).

Animals should be sacrificed at the end of the study and the observation parameters should include (Dams) body weight, food intake, general signs of intoxication, progress of gestation/ parturition periods and gross pathology (if any); and for pups, the clinical signs, sex-wise distribution in dose groups, body weight, growth parameters, gross examination, survival and autopsy (if needed) and where necessary, histopathology.

1.4 Local toxicity

These studies (see Appendix I, item 4.5) are required when the new drug is proposed to be used by some special route (other than oral) in humans. The drug should be applied to an appropriate site (e.g., skin or vaginal mucous membrane) to determine local effects in a suitable species. Typical study designs for these studies should include three dose levels and untreated and/ or vehicle control, preferably use of 2 species, and increasing group size with increase in duration of treatment. Where dosing is restricted due to anatomical or humane reasons, or the drug concentration cannot be increased beyond a certain level due to the problems of solubility, pH or tonicity, a clear statement to this effect should be given. If the drug is absorbed from the site of application, appropriate systemic toxicity studies will also be required.

Notes:

(i) Dermal toxicity study: The study should be done in rabbit and rat. Daily topical (dermal) application of test substance in its clinical dosage form should be done. Test material should be applied on shaved skin covering not less than 10% of the total body surface area. Porous gauze dressing should be used to hold liquid material in place. Formulations with different concentrations (at least 3) of test substance, several fold higher than the clinical dosage form should be used. Period of application may vary from 7 to 90 days depending on the clinical duration of use. Where skin irritation is grossly visible in the initial studies, a recovery group should be included in the subsequent repeated-dose study. Local signs (erythema, oedema and eschar formation) as well as histological examination of sites of application should be used for evaluation of results.

(ii) Photo-allergy or dermal photo-toxicity: It should be tested by Armstrong/ Harber Test in guinea pig. This test should be done if the drug or a metabolite is related to an agent causing photosensitivity or the nature of action suggests such a potential (e.g., drugs to be used in treatment of leucoderma). Pretest in 8 animals should screen 4 concentrations (patch application for 2 hours $\pm$15 min.) with and without UV exposure (10 J/cm^2). Observations recorded at 24 and 48 hours should be used to ascertain highest nonirritant dose. Main test should be performed with 10 test animals and 5 controls. Induction with the dose selected from pretest should use 0.3 ml/patch for 2 hour $\pm$15 min. followed by 10 J/cm^2 of UV exposure. This should be repeated on day 0, 2,4,7,9 and 11

of the test. Animal should be challenged with the same concentration of test substance between day 20 to 24 of the test with a similar 2-hour application followed by exposure to 10 J/cm^2 of UV light. Examination and grading of erythema and oedema formation at the challenge sites should be done 24 and 48 hours after the challenge. A positive control like musk ambrett or psoralin should be used.

(iii) vaginal Toxicity Test: Study is to be done in rabbit or dog. Test substance should be applied topically (vaginal muscoas) in the form of pessary, cream or ointment. Six to ten animals per dose group should be taken. Higher concentrations or several daily applications of test substance should be done to achieve multiples of daily human dose. The minimum duration of drug treatment is 7 days (more according to clinical use) Subject to a maximum of 30 days. Observation parameters should include swelling, closure of introitus and histopathology of vaginal wall.

(iv) Rectal Tolerance Test: For all preparations meant for rectal administration this test may be performed in rabbits or dogs. Six to ten animals per dose group should be taken. Formulation in volume comparable to human dose (or the maximum possible volue) should be applied once or several times daily, per rectally, to achieve administration of multiples of daily human dose. The minimum duration of application is 7 days (more according to clinical use), Subject to a maximum of 30 days. Size of suppositories may be smaller, but the drug content should be several fold higher than the proposed human dose. Observation parameters should include clinical signs (sliding on backside), sings of pain, blood and/ or mucus in faeces, condition of anal region/ sphincter, gross and (if required) histoligical examination of rectal mucosa.

(v) Parenteral Drugs: For products meant for intravenous or intramuscular or subcultaneous or intradermal injection the sites of injection in systemic toxicity studies should be specially examined grossly and microscopically. If needed, reversibility of adverse effects may be determined on a case to case basis.

(vi) Ocular toxicity studies (for products meant for ocular instillation): These studies should be carried out in two species, one of which should be the albino rabbit which has a sufficiently large conjunctival sac. Direct delivery of durg onto the cornea in case of animals having small conjunctival sacs should be ensured. Liquids, ointments, gels or soft contact lenses (saturated with drug) should be used. Initial single dose application should be done to decide the exposure concentrations for repeated-dose studies and the need to include a recovery group. Duration of the final study will depend on the proposed length of human exposure Subject to a maximum of 90 days. Atleast two different concentrations exceeding the human dose should be used for demonstrating the margin of safety. In acute studies, one eye should be used for drug administration and the other kept as control. A separate control group should be included in repeated-dose studies.

Slit-lamp examination should be done to detect the changes in cornea, iris and aqueous humor. Fluorescent dyes (sodium fluorescein, 0.25 to 1.0%) should be used for detecting the defects in surface epithelium of cornea and conjunctiva. Changes in intra-ocular tension should be monitored by a tonometer. Histological examination of eyes should be done at the end of the study after fixation in davidson's or Zenker's fluid.

(vii) Inhalation toxicity studies: The studies are to be undertaken in one rodent and one non-rodent species using the formulation that is to be eventually proposed to be marketed. Acute, subacute and chronic toxicity studies should be performed according to the intended duration of human exposure. Standard systemic toxicity study designs (described above) should be used. Gases and vapors should be given in whole body exposure chambers; aerosols are to be given by nose-only method. Exposure time and concentrations of test substance (limit dose of 5mg/ l) should be adjusted to ensure exposure at levels comparable to multiples of intended human exposure. Three dose groups and a control (plus vehicle control, if needed) are required. Duration of exposure may vary Subject to a maximum of 6 hours per day and five days a week. Food and water should be withdrawn during the period of exposure to test substance.

Temperature, humidity and flow rate of exposure chamber should be recorded and reported. Evidence of exposure with test substance of particle size of 4 micron

(especially for aerosols) with not less that 25% being 1 micron should be provided. Effects on respiratory rate, findings of bronchial lavage fluid examination, histological examination of respiratory passages and lung tissue should be included along with the regular parameters of systemic toxicity studies or assessment of margin of safety.

1.5 Allergenicity/ Hypersensitivity:

Standard tests include guinea pig maixmization test (GPMT) and local lymph node assay (LLNA) in mouse. Any one of the two may be done.

Notes:

(i) Guinea Pig Maximization Test: The test is to be performed in two steps; first, determination of maximum nonirritant and minimum irritant doses, and second, the main test. The initial study will also have two components. To determine the intradernal induction dose, 4 dose levels should be tested by the same route in a batch of a 4 male and 4 female animals (2 of each sex should be given Freund's adjuvant). The minimum irritant dose should be used for induction. Similarly, a topical minimum irritant dose should be determined for challenge. This should be established in 2 males and 2 females. A minimum of 6 male and 6 female animals per group should be used in the main study. One test and one control group should be used. It is preferable to have one more positive control group. Intradermal induction (day 1) coupled with topical challenge (day 21) should be done. If there is no response, re-challenge should be done 7-30 days after the primary challenge. Erythema and oedema (individual animal scores as well as maximization grading) should be used as evaluation criteria.

(ii) Local Lymph Node Assay: Mice used in this test should be of the same sex, either only males or only females. Drug treatment is to be given on ear skin. Three graded doses, the highest being maximum nonirritant dose plus vehicle control should be used. A minimum of 6 mice per group should be used. Test material should be applied on ear skin on three consecutive days and on day 5, the draining auricular lymph nodes should be dissected out 5 hours after i.v. ^{3}H-thymidine or bromo-deoxy-uridine (BrdU). Increase in ^{3}H-thymidine or Brdu incorporation should be used as the criterion for evaluation of results.

1.6 Genotoxicity

Genotoxic compounds, in the absence of other data, shall be presumed to be transpecies carcinogens, implying a hazard to humans. Such compounds need not be Subjected to long-term carcinogenicity stuides. However, if such a drug is intended to be administered for chronic illnesses or otherwise over a long period of time- a chronic toxicty study (up to one year) may be necessary to detect early tumorigenic effects.

Genotoxicity tests are in vitro and in vivo tests conducted to detect compounds which induce genetic damage directly or indirectly. These tests should enable a hazard identification with respect to damage to DNA and its fixation.

The following standard test battery is generally expected to be conducted:

(i) A test for gene mutation in bacteria.

(ii) An in vitro test with cytogenetic evaluation of chromosomal damage with mammalian cells or an in vitro mouse lymphoma tk assay

(iii) An in vivo test for chromosomal damage using rodent hematopoietic cells.

Other genotoxicity tests e.g. tests for measurement of DNA adducts, DNA strand breaks, DNA repair or recombination serve as options in addition to the standard battery for further investigation of genotoxicity test results obtained in the standard battery. Only under extreme conditions in which one or more tests comprising the standard battery cannot be employed for technical reasons, alternative validated tests can serve as substitutes provided sufficient scientific justification should be provided to support the argument that a given standard battery test is not appropriate.

Both in-vitro and in-vivo studies should be done. In-vitro studies should include Ame's Salmonella assay and chromosomal aberrations (CA) in cultured cells. In-vivo studies should include micronucleus assay (MNA) or CA in rodent bone marrow. Data analysis of CA should include analysis of 'gaps.'

Cytotoxic anticancer agents: Genotoxicity data are not required before Phase I and II trials. But these stuides should be completed before a0pplying for Phase III trials.

Notes:

Ames' Test (Reverse mutation assay in Salmonella): S. typhimurium tester strains such as TA98, TA100, TA102, TA1535, TA97 or *Escherichia coli* WP2 uvrA or Escherichia coli WP2 uvrA (pKM101) should be used.

(i) In-vitro exposure (with and without metabolic activation, S9 mix) should be done at a minimum of 5 log dose levels. "Solvent" and "positive" control should be used. Positive control may include 9-amino-acridine, 2-nitrofluorine, sodium azide and mitomycin C, respectively, in the tester strains mentioned above. Each set should consist of at least three replicates. A 2.5 fold (or more) increase in number of revertaints in comparison to spontaneous revertants would be considered positive.

(ii) In-vitro cytogenetic assay: The desired level of toxicity for *in vitro cytogenetic* tests using cell lines should be greater than 50% reduction in cell number or culture confluency. For lymphocyte cultures, an inhibition of mitotic index by greater than 50% is considered sufficient. It should be performed in CHO cells or on human lymphocyte in culture. In-vitro exposure (with and without metabolic activation, S9 mix) should be done using a minimum of 3 log doses. "Solvent" and "positive" control should be included. A positive control like Cyclophosphamide with metabolic activation and Mitomycin C for without metabolic activation should be used to give a reproducible and detectable increase clastogenic effect over the background which demonstrates the sensitivity of the test system. Each set should consist of at least three replicates. Increased number of aberrations in meta Phase chromosomes should be used as the criteria for evaluation.

(iii) In-vivo micronumclus assay: One rodent species (preferably mouse) is needed. Route of administration of test substance should be the same as intended for humans. Five animals per sex per dose groups should be used. At least three dose levels, plus "solvent" and "positive" control should be tested. A positive control like mitomycin C or cyclophosphamide should be used. Dosing should be done on day 1 and 2 of study followed by sacrifice of animals 6 hours after the last injection. Bone marrow from both the femora should be taken out, flushed with fetal bovine serum (20 min.), pelletted and smeared on glass slides. Giemsa-May Gruenwald staining should be done and increased number of micronuclei in polychromatic erythrocytes (minimum 1000) should be used as the evaluation criteria.

(iv) In-vivo cytogenetic assay: One rodent species (preferably rat) is to be used. Route of administration of test substance should be the same as intended for humans. Five animals/ sex/ dose groups should be used. At least three dose levels, plus "solvent" and "positive" control should be tested. Positive control may include cyclophosphamide. Dosing should be done on day 1 followed by intra-peritoneal colchicine administration at 22 hours. Animals should be sacrificed 2 hours after colchicine administration. Bone marrow from both the femora should be taken out, flushed with hypotonic saline (20 min.) pelletted and resuspended in Carnoy's fluid. Once against the cells should be pelletted and dropped on clean glass slides with a Pasteur pipette. Giemsa staining should be done and increased number of aberrations in meta Phase chromosomes (minimum 100) should be used as the evaluation criteria.

1.7 Carcinogenicity (See Appendix I, item 4.8)

Carcinogenicity studies should be performed for all drugs that are expected to be clinically used for more than 6 months as well as for drugs used frequently in an intermittent manner in the treatment of chronic or recurrent conditions. Carcinogenicity studies are also to be performed for drugs if there is concern about their carcinogenic potential emanating from previous demonstration of carcinogenic potential in the product class that is considered relevant to humans or where structure-activity relationship suggests carcinogenic risk or when there is evidence of preneoplastic lesions in repeated dose toxicity studies or when long-term tissue retention of parent compound or metabilite(s) results in local tissue reactions or other pathophsiological responses. For pharmaceuticals developed to treat certain serious diseases, Licensing Authority may allow carcinogenicity testing to be conducted after marketing permission has been granted.

In instances where the life-expectancy in the indicated population is short (i.e., less than 2-3 year)- no long-term carcinogenicity studies may be required. In cases where the therapeutic agent for cancer is generally successful and life is significantly prolonged there may be later concerns regarding secondary cancers. When such drugs are intended for adjuvant therapy in tumour free patients or for prolonged use in non-cancer indications, carcinogenicity studies may be/ are needed. Completed rodent carcinogenicity studies are not needed in advance of the conduct of large scale 'clinical trials, unless there is special concern for the patient population.

Carcinogenicity studies should be done in a rodent species (preferably rat). Mouse may be employed only with proper scientific justification. The selected strain of animals should not have a very high or very low incidence of spontaneous tumors.

At least three dose levels should be used. The highest dose should be sub-lethal, and it should not reduce the life span of animals by more than 10% of expected normal. The lowest dose should be comparable to the intended human therapeutic dose or a multiple of it, e.g. 2.5x; to make allowance for the sensitivity of the species. The intermediate dose to be placed logarithmically between the other two doses. An untreated control and (if indicated) a vehicle control group should be included. The drug should be administered 7 days a week for a fraction of the life span comparable to the fraction of human life span over which the drug is likely to be used therapeutically. Generally, the period of dosing should be 24 months for rats and 18 months for mice.

Observations should include macroscopic changes observed at autopsy and detailed histopathology of organs and tissues. Additional tests for carcinogenicity (short-term bioassays, neonatal mouse assay or tests employing transgenic animals) may also be done depending on their applicability on a case to case basis.

Note:

Each dose group and concurrent control group not intended to be sacrificed early should contain atleast 50 animals of each sex. A high dose sattelite group for evaluation of pathology other than neoplasia should contain 20 animals of each sex while the sattelite control group should contain 10 animals of each sex. Observation parameters should include signs of intoxication, effect on body weight, food intake, clinical chemistry parameters, hematology parameters, urine analysis, organ weights, gross pathology and detailed histopathology. Comprehensive descriptions of benign and malignant tumour development, time of their detection, site dimensions, histological typing etc. should be given.

1.8 Animal toxicity requirements for clinical trials and marketing of a new drug.

Systemic Toxicity Studies			
Route of administration	Duration of proposed human administration	Human Phase(s) for which study is proposed to be conducted	Long term toxicity requirements
1	2	3	4
Oral or Parenteral or Transdermal	Single dose or several doses in one day, Upto 1wk	I, II, III	2sp, 2wk
	>1wk but upto 2wk	I, II, III	2sp; 4wk
	>2 wk but upto 4 wk	I, II, III	2sp; 12wk
	Over 1mo	I, II, III	2sp; 24wk
Inhalation (general anaesthetics, aerosols)	Upto 2 wk	I, II, III	2sp; 1mo; (Exposure time 3h/d, 5d/wk)
	Upto 4wk	I, II, III	2sp; 12wk, (Exposure time 6h/d, 5d/wk)
	>1 4wk	I, II, III	2sp; 24wk, (Exposure time 6h/d, 5d/wk

1	2	3	4
Local Toxicity Studies			
Dermal	Upto 2 wk	I, II	1sp;4wk
		III	2sp;4wk
	>2wk	I,II,III	2sp;12wk
Ocular or Otic or Nasal	Upto 2wk	I,II	1sp;4wk
		III	2sp; 4wk
	>2wk	I,II,III	2sp;12wk
Vaginal or Rectal	Upto 2 wk	I,II	1sp;4wk
		III	2sp;4wk
	>2wk	I,II,III	2sp;12wk

Special Toxicity Stuides

Male Fertility Study:

- Phase I, II, III in male volunteers/ patients

Female Reproduction and Developmental Toxicity Studies:

- Segment II studies in 2 species, Phase II, III involving female patients of childbearing age.
- Segment I study; Phase III involving female patients of child-bearing age.
- Segment III study; Phase III for drugs to be given to pregnant or nursing mothers for long periods or where there are indications of possible adverse effects on foetal development.

Allergenicity/ Hypersensitivity:

- Phase I, II, III-when there is a cause of concern or for parenteral drugs (including dermal application)

Photo-allergy or dermal photo-toxicity:

- Phase I, II, III-if the drug or a metabolite is related to an agent causing photosensitivity or the nature of action suggests such a potential.

Genotoxicity:

- In-vitro studies-Phase I
- Both in-vitro and in-vivo-Phase II, III

arcinogenicity:

- Phase III-when there is a cause for concern, or when the drug is to be used for more than 6 months.

Abbreviations: sp-species; mo-month; wk-week; d-day; h-hour; I, II, III-Phases of clinical trial;

Note:	1. Animal toxicity data generated in other countries may be accepted and may not be asked to be repeated/ duplicated in India on a case to case basis depending upon the quality of data and the credentials of the laboratory (ies) where such data has been generated.
	2. Requirements for fixed dose combinations are given in Appendix VI.
1.9	Number of animals required for repeated-dose toxicity studies

	14-28 days				84-182 days			
Group	Rodent (Rat)		Non-rodent (Dog or Monkey)		Rodent (Rat)		Non-rodent (Dog or Monkey)	
1	2		3		4		5	
	M	F	M	F	M	F	M	F
Control	6-10	6-10	2-3	2-3	15-30	15-30	4-6	4-6
Low dose	6-10	6-10	2-3	2-3	15-30	15-30	4-6	4-6

1	2		3		4		5	
Intermediate dose	6-10	6-10	2-3	2-3	15-30	15-30	4-6	4-6
High dose	6-10	6-10	2-3	2-3	15-30	15-30	4-6	4-6

2.0	Laboratory parameters to be included in toxicity stuides. Haematological parameters		
• Haemoglobin	• Total RBC Count	• Haematocrit	• Reticulocyte
• Total WBC Count	• Differential WBC Count	• Platelet Count	• Terminal Bone Marrow Examination
• ESR (Non-rodents only)	• General Blood Picture: A special mention of abnormal and immature cells should be made.		
• Coagulation Parameters (Non-rodents only): Bleeding Time, Coagulation Time, Prothrombin Time, Activated Partial Thromboplastin Time.			
Urinalysis Parameters			
• Colour	• Appearance	• Specific Gravity	• 24-hour urinary output
• Reaction (pH)	• Albumin	• Sugar	• Acetone
• Bile pigments	• Urobilinogen	• Occult Blood	
• Microscopic examination of urinary sediment.			
Blood Biochemical Parameters			
• Glucose	• Cholesterol	• Triglycerides	• HDL Cholesterol (Non-rodents only)
• LDL	• Bilirubin	• SGPT(ALT)	• SGOT
Cholesterol (Non-rodents only)			(AST)
• Alkaline Phosphatase (ALP)	• GGT (Non-rodents only)	• Blood Urea Nitrogen	• Creatinine
• Total Proteins	• Albumin	• Globulin (Calculated valuves)	• Sodium
• Potassium	• Phosphorus	• Calcium	
Gross and Microscopic Pathology			
• Brain Cerebrum, cerebellum, Midbrain	• (Spinal Cord)	• Eye	• (Middle Ear)
• Thyroid	• (Parathyroid)	• Spleen*	• Thymus
• Adrenal*	• (Pancreas)	• (Trachea)	• Lung*
• Heart*	• Aorta	• Oesophagus	• Stomach
• Duodenum	• Jejunum	• Terminal ileum	• Colon
• (Rectum)	• Liver*	• Kidney*	• Urinary bladder
• Epididymis	• Testis*	• Ovary	• Uterus*
• Skin	• Mammary gland	• Mesenteric lymph node	• Skeletal muscle

* Orgnas marked with an asterisk should be weighed. () Organs listed in parenthesis should be examined if indicated by the nature of the drug or observed effects. Non-clinical toxicty testing and safety evaluation data of an IND needed for the conduct of different phases of clinical trials.

Note: Refer Appendix III (Points 1.1 through 1.7 and tables 1.8 and 1.9) for essential features of study designs of the non-clinical toxicity studies listed below:

For Phase I Cinical Trials

Systemic Toxicity studies

i. Single dose toxicity studies

ii. Dose Ranging Studies

iii. Repeat-dose systemic toxicity studies of appropriate duration to support the duration to support the duration of proposed human exposure.

Male fertility study

In-vitro genotoxicity tests

Relevant local toxicity studies with proposed route of clinical application (duration depending on proposed length of clinical exposure)

Allergenicity/ Hypersensitivity tests (when there is a cause for concern or for parenteral drugs, including dermal application)

Photo-allergy or dermal photo-toxicity test (if the drug or a metabolite is related to an agent causing photosensitivity or the nature of action suggests such a potential)

For Phase II Clinical Trials

Provide a summary of all the non-clinical safety data (listed above) already submitted while obtaining the permissions for Phase I trial, with appropriate references.

In case of an application for directly starting a Phase II trial- complete details of the non-clinical safety data needed for obtaining the permission for Phase I trial, as per the list provided above must be submitted.

Repeat-dose systemic toxicity studies of appropriate duration to support the duration of proposed human exposure.

In-vivo genotoxicity tests

Segment II reproductive/ developmental toxicity study (if female patients of child bearing age are going to be involved)

For Phase III Clincial Trials

Provide a summary of all the non-clinical safety data (listed above) already submitted while obtaining the permissions for Phase I and II trials, with appropriate references.

In case of an application for directly initiating a Phase III trial-complete details of the non-clinical safety data needed for obtaining the permissions for Phase I and II trials, as per the list provided above must be provided.

Repeat-dose systemic toxicity studies of appropriate duration to support the duration of proposed human exposure.

Reproductive/ developmental toxicity studies

Segment I (if female patients of child bearing age are going to be involved), and

Segment III (for drugs to be given to pregnant or nursing mothers or where there are indications of possible adverse effects on foetal development)

Carcinogenicity studies (when there is a cause for concern or when the drug is to be used for more than 6 months)

For Phase IV Clinical Trials

Provide a summary of all the non-clinical safety data (listed above) already submitted while obtaining the permissions for Phase I, II and III trials, with appropriate references.

In case an application is made for initiating the Phase IV trials, complete details of the non-clinical safety data needed for obtaining the permissions for Phase I, II and III trials, as per the list provided above must be submitted.

Application of Good Laboratory Practices (GLP)

The animal studies be conducted in an accredited laboratory. Where the safety pharmacology studies are part of toxicology studies, these studies should also be conducted in an accredited laboratory.

Appendix-IV
ANIMAL PHARMACOLOGY

1. General Principles

Specific and general pharmacological studies should be conducted to support use of therapeutics in humans. In the early stages of drug development enough information may not be available to rationally select study design for safety assessment. In such a situation, a general approach to safety pharmacology studies can be applied. Safety pharmacology studies are studies that investigate potential undesirable pharmacodynamic effects of a substance on physiological functions in relation to exposure within the therapeutic range or above.

1.1 Specific Pharmacological Actions

Specific pharmacological actions are those which demonstrate the therapeutic potential for humans.

The specific studies that should be conducted and their design will be different based on the individual properties and intended uses of investigational drug.

Scientifically validated methods should be used. The use of new technologies and methodologies in accordance with sound scientific principles should be preferred.

1.2 General Pharmacological Actions

1.2.1 Essential Safety Pharmacology.

Safety pharmacology studies need to be conducted to investigate the potential undersirable pharmacodynamic effects of a substance on physiological functions in relation to exposure within the therapeutic range and above. These studies should be designed to identify undersirable pharmacodynamic properites of a sustance that may have relevance to its human safety; to evaluate adverse pharmacodynamic and/ or pathophysilogical effects observed in toxicology and/ or clinical studies; and to investigate the mechanism of the adverse pharmacodynamic effects observed and/ or suspected.

The aim of the essential safety pharmacology is to study the effects of the test drug on vital functions. Vital organ systems such as cardiovascular, respiratory and central nervous systems should be studied. Essential safety pharmachology studies may be excluded or supplemented based on scientific rationale. Also, the exclusion of certain tests(s) or exploration(s) of certain organs, systems or functions should be scientifically justified.

1.2.1.1. Cardiovascular System:

Effects of the investigational drug should be studied on blood pressure, heart rate, and the electrocardiogram. If possible in vitro, in vivo and/ or ex vivo methods include electrophysiology should also be considered.

1.2.1.2. Central Nervous System:

Effects of the investigational drug should be studied on motor activity, behavioral changes, coordination, sensory and motor reflex responses and body temperature.

1.2.1.3. Respiratory System

Effects and of the investigational drug on respiratory rate and other functions such as tidal volume and hemoglobin oxygen saturation should be studied.

1.3. Follow-up and Supplemental Safety Pharmacology Studies

In addition to the essential safety pharmacological studies, additional supplemental and follow-up safety parmacology studies may need to be conducted as appropriate. These depend on the pharmacological properties or chemical class of the test substance, and the data generated from safety pharmacology studies, clinical trials pharmacovigilance, experimetal in vitro or in vivo studies, or from literature reports.

1.3.1 Follow-up Studies For Essential Safety Pharmacology

Follow-up studies provide additional information or a better understanding than that provided by the essential safety pharmacology.

1.3.1.1 Cardiovascular System:

These include ventricular contractility, vascular resistance and the effects of chemical mediators, their agonists and antagonists on the cardiovascular system.

1.3.1.2 Central Nervous System:

These include behavioral studies, learning and memory, electrophysiology studies, neurochemistry and ligand binding studies.

1.3.1.3 Respiratory System:

These include airway resistance, compliance, pulmonary arterial pressure, blood gases and blood pH.

1.3.2 Supplemental Safety Pharmacology Studies

These studies are required to investigate the possible adverse pharmacological effects that are not assessed in the essential safety pharmacological studies and are a cause for concern.

1.3.2.1 Urinary System

These include urine volume, specific gravity, osmolality, pH, proteins, cytology and blood urea nitrogen, creatinine and plasma proteins estimation.

1.3.2.2 Autonomic Nervous System:

These include binding to receptors relevant for the authonomic nervous system, and functional response to agonist or antagonist responses in vivo or in vitro, and effects of direct stimulation of autonomic nerves and their effects on cardiovascular responses.

1.3.2.3 Gastrointestinal System

These include studies on gastric secretion, gastric pH measurement, gastric mucosal examination, bile secretion, gastric emptying time in vivo and ileocaecal contraction in vitro.

1.3.2.4 Other Organ Systems:

Effects of the investigational drug on organ systems not investigated elsewhereshould be assessed when there is a cause for concern. For example dependency potential, skeletal muscle, immune and endocrine functions may be investigated.

1.4 Conditions Under Which Safety Pharmacology Studies Are Not Necessary

Safety pharmacology studies are usually not required for locally applied agents e.g. dermal or ocular, in cases when the pharmacology of the investigational drug is well known, and/ or when systemic absorption from the site of application is low. Safety pahrmacology testing is also not necessary, in the case of a new derivative having similar pharmacokinetics and pharmacodynamics.

1.5 Timing Of Safety Pharmacology Studies In Relation To Clinical Development.

1.5.1 Prior To First Administration In Humans

The effects of an investigational drug on the vital functions listed in the essential safety pharmacology should be studied prior to first administration in humans. Any follow-up or supplemental studies identified, should be conducted if necessary, based on a cause for concern.

1.5.2 During Clinical Development.

Additional investigations may be warranted to clarify observed or suspected adverse effects in animals and humans during clinical development.

1.5.3 Before applying for marketing Approval.

Follow-up and supplemental safety pharmacology studies should be assessed prior to approval unless not required, in which case this should be justified. Available information from toxicology studies addressing safety pharmacology endpoints or information from clinical studies can replace such studies.

1.6. Application Of Good Laboratory Practices (GLP)

The animal studies be conducted in an accredited laboratory. Where the safety pharmacology studies are part of toxicology studies, these studies should also be conducted in an accredited laboratory.

APPENDIX-V
INFORMED CONSENT

1. Checklist for study Subject's informed consent documents

1.1. Essential Elements:

1. Statement that the study involves research and explanation of the purpose of the research.
2. Expected duration of the Subject's participation
3. Description of the procedures to be followed, including all invasive procedures and
4. Description of any reasonably foreseeable risks or discomforts to the Subject.
5. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
7. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.
8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)

9. Compensation and/ or treatment(s) available to the Subject in the event of a trial-related injury.
10. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.
11. The anticipated prorated payment, if any, to the Subject for participating in the trial
12. Subject's responsibilities on participation in the trial.
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled
14. Any other pertinent information

1.2 Additional elements, which may be required

a. Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.
b. Additional costs to the Subject that may result from participation in the study.
c. The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
d. Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.
e. A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable
f. Approximate number of Subjects enrolled in the study

2. Format of informed consent form for Subjects participating in a clinical trial.
Informed Consent form to participate in a clinical trial

Study Title:

Study Number:

Subject's Initials:____________ Subject's Name:______________

Date of Birth/ Age: __________

Please initial box (Subject)

(i) I confirm that I have read and understood the information sheet dated_____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reasons, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/ Legally Acceptable Representative:___________
Date:_____/_____/_______

Signatory's Name:____

Signature of the Investigator:________________________________Date:____/_____/_____

Study Investigator's Name:____

Signature of the Witness ____________________________Date:_______/_____/______

Name of the Witness:____

APPENDIX-VI

FIXED DOSE COMBINATIONS (FDCs)

Fixed Dose Combinations refer to products containing one or more active ingredients used for a particular indication(s). FDCs can be divided into the following groups and data required for approval for marketing is described below:

(a) The first group of FDCs includes those in which one or more of the active ingredients is a new drug. For such FDCs to be approved for marketing data to be submitted will be similar to data required for any new drug (including clinical trials) [see rule 122E, item (a)].

(b) (i) The second group FDCs includes those in which active ingredients already approved/ marketed individually are combined for the first time for a particular claim and where the ingredients are likely to have signaificant interaction of a pharmacodynamic or pharmacokinetic nature [See rule 122E, item (c)]. If clinical trials have been carried out with the FDC in other countries, reports of such trials should be submitted. If the FDC is marketed abroad, the regulatory status in other countries should be stated. (see Appendix I, item 9).

(ii) For marketing permission, appropriate chemical and pharmaceutical data will be submitted. In case such a combination is not marketed anywhere in the world but these drugs are already in use concomitantly (not as an FDC but individually) for the said claim, marketing permission may be granted based on chemical and pharmaceutical data. Data showing the stability of the proposed dosage form will also have to be submitted.

(iii) For any other such FDCs, clinical trials may be required. For obtaining permission to carry out clinical trials with such FDCs a summary of available pharmacological, toxicological and clinical data on the individual ingredients should be submitted, along with the rationale for combining them in the proposed ratio. In addition, acute toxicity data (LD 50) and pharmacological data should be submitted on the individual ingredients as well as their combination in the proposed ratio.

(c) The third group of FDCs includes those which are already marketed, but in which it is proposed either to change the ratio of active ingredients or to make a new therapeutic claim. For such FDCs, the appropriate rationale including published reports (if any) should be submitted to obtain marketing permission. Permission will be granted depending upon the nature of the claim and data submitted.

(d) The fourth group of FDC includes those whose individual active ingredients (or drugs from the same class) have been widely used in a particular indication(s) for years, their concomitant use is often necessary and no claim is proposed to be made other than convenience. It will have to be demonstrated that the proposed dosage form is stable and the ingredients are unlikely to have significant interaction of a pharmacodynamic or pharmacokinetic nature.

No additional animal or human data are generally required for these FDCs, and marketing permission may be granted if the FDC has an acceptable rationale.

APPENDIX-VII

UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)
2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, and / or only other statement(s) of qualification (s))
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation(s).
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Commitments:
   (i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
   (ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval/ favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.
   (iii) I agree to personally conduct and/ or supervise the clinical trial at my site.
   (iv) I agree to inform all Subjects, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines are met.
   (v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory and GCP guidelines.
   (vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
   (vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
   (viii) I agree to maintain adequate and accurate records and to make those records available for audit/ inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
   (ix) I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
   (x) I agree to inform all unexpected serious adverse events to the Sponsor as well as the Ethics Committee within seven days of their occurance.
   (xi) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.
   (xii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

Signature of Investigator with Data

APPENDIX-VIII

ETHICS COMMITTEE

1. The number of persons in an Ethcis Committee should have atleast seven members. Ethics Committee should appoint, from among it members, a Chairperson (who is from outside the institution) and Member Secretary. Other members should be a mix of medical/ non-medical, scientific and non-scientific persons, including lay public, to reflect the different viewpoints.
   For review of each protocol the quorum of Ethics Committee should be atleast 5 members with the following representations:
   (a) basic medical scientists (preferably one pharmacologist).
   (b) clinicians
   (c) legal expert
   (d) social scientist/ representative of non-governmental voluntary agency/ philosopher/ ethicist/ theologian or a similar person
   (e) lay person from the community.

In any case, the ethics committee must include at least one member whose primary area of interest/ specialization is nonscientific and at least one member who is independent of the institution/ trial site. Besides, there should be appropriate gender representation on the Ethics Committee. If required, Subject experts may be invited to offer their views. Further, based on the requirement of research area, e.g. HIV AIDS, genetic disorders etc. specific patient groups may also be represented in the Ethics Committee as far as possible.

Only those Ethics Committee members who are independent of the clinical trial and the Sponsor of the trial should vote/ provide opinion in matters related to the study.

2. Format for Approval of Ethics Committee

To

Dr.

Dear Dr._______

The Institutional Ethics Committee/ Independent Ethics Committee (state name of the committee, as appropriate) reviewed and discussed your application to conduct the clinical trial entitled ".....''on.....(date).

The following documents were reviewed:

a. Trial Protocol (including protocol amendments), dated_________Version no(s)._______
b. Patient Information Sheet and Informed Consent Form (including updates if any) in English and/ or vernacular language.
c. Investigator's Brochure, dated________, Version no.___________
d. Proposed methods for patient accrual including advertisement(s) etc. proposed to be used for the purpose.
e. Principal Investigator's current CV.
f. Insurance Policy/ Compensation for participation and for serious adverse events occurring during the study participation.
g. Investigator's Agreement with the Sponsor.
h. Investigator's Undertaking (Appendix VII).

The following members of the ethics committee were present at the meeting held on (date, time, place).

_______________Chairman of the Ethics Committee

_______________ Member secretary of the Ethics Committee

_______________ Name of each member with designation

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee/ Independent Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/ informed consent and asks to be provided a copy of the final report.

Yours sincerely,

Member Secretary, Ethics Committee.

APPENDIX-IX

STABILITY TESTING OF NEW DRUGS

Stability testing is to be performed to provide evidence on how the quality of a drug substance or formulation varies with time under the influence of various environmental factors such as temperature, humidity and light and to establish shelf life for the formulation and recommended storage conditions.

Stability studies should include testing of those attributes of the drug substance that are susceptible to change during storage and are likely to influence quality, safety, and/ or efficiency. In case of formulations the testing should cover, as appropriate, the physical, chemical, biological, and microbiological attributes, preservative content (e.g., antioxidant, antimicrobial preservative), and functionality tests (e.g., for a dose delivery system).

Validated stability-indicating analytical procedures should be applied. For long term studies, frequency of testing should be sufficient to establish the stability profile of the drug substance.

In general, a drug substance should be evaluated under storage conditions that test its thermal stability and, if applicable, its sensitivity to moisture. The storage conditions and the length of studies chosen should be sufficient to cover storage, shipment and subsequent use.

Stress testing of the drug substance should be conducted to identify the likely degradation products, which in turn establish the degradation pathways, evaluate the intrinsic stability of the molecule

and validate the stability indicating power of the analytical procedures used. The nature of the stress testing will depend on the individual drug substance and the type of formulation involved.

Stress testing may generally be carried out on a single batch of the drug substance. It should include the effect of temperatures), humidity where appropriate, oxidation, and photolysis on the drug substance.

Data should be provided for (a) Photostability on at least one primary batch of the drug substance as well as the formulation, as the case may be and (b) the susceptibility of the drug substance to hydrolysis across a wide range of pH values when in solution or suspension.

Long-term testing should cover a minimum of 12 months duration on at least three primary batches of the drug substance or the formulation at the time of submission and should be continued for a period of time sufficient to cover the proposed shelf life. Accelerated testing should cover a minimum of 6 months duration at the time of submission.

In case of drug substances, the batches should be manufactured to a minimum of pilot scale by the same synthetic route and using a method of manufacture that simulates the final process to be used for production batches. In case of formulations, two of the three batches should be at least pilot scale and the third one may be smaller. The manufacturing process(es) used for primary batches should simulate that to be applied to production batches and should provide products of the same quality and meeting the same specifications as that intended for marketing.

The stability studies for drug substances should be conducted either in the same container-closure system as proposed for storage and distribution or in a container-closure system that simulates the proposed final packaging. In case of formulations, the stability studies should be conducted in the final container-closure system proposed for marketing.

Stability Testing of new drug substances and formulations:

(i) Study conditions for drug substances and formulations intended to be stored under general conditions.

Study	Study conditions	Duration of study
Long term	$30^0C\pm2^0C$/65% RH$\pm$5% RH	12 months
Accelerated	$40^0C\pm2^0C$/ 75% RH$\pm$ 5% RH	6 months

If at any time during 6 month's testing under the accelerated storage condition, such changes occur that cause the product to fail in complying with the prescribed standards, additional testing under an intermediate storage condition should be conducted and evaluated against significant change criteria.

(ii) Study conditions for drug substances and formulations intended to be stored in a refrigerator

Study	Study conditions	Duration of study
Long term	$5^0C\pm3^0C$	12 months
Accelerated	$25^0C\pm2^0C$/60% RH$\pm$ 5% RH	6 months

(iii) Study conditions for drug substances and formulations intended to be stored in a freezer.

Study	Study conditions	Duration of study
Long term	$-20^0C\pm5^0C$	12 months

(iv) Drug substances intended for storage below -20^0C shall be treated on a case-by-case basis.

(v) Stability testing of the formulation after constitution or dilution, if applicable, should be conducted to provide information for the labeling on the preparation, storage condition, and in-use period of the constituted or diluted product. This testing should be performed on the constituted or diluted product through the proposed in-use period.

APPENDIX-X

CONSTENTS OF THE PROPOSED PROTOCOL FOR CONDUCTING CLINICAL TRIALS

1, Title Page

a. Full title of the clinical study.
b. Protocol/ Study number, and protocol version number with date
c. The IND name/ number of the investigational drug
d. Complete name and address of the Sponsor and contract research organization if any
e. List of the Investigators who are conducting the study, their respective institutional affiliations and site locations.
f. Name(s) of clinical laboratories and other departments and/ or facilities participating in the study.

2. Table of Contents
   A complete Table of Contents including a list of all Appendices.
1. Background and Introduction
   a. Preclinical experience
   b. Clinical experience
      Previous clinical work with the new drug should be reviewed here and a description of how the current protocol extends existing data should be provided. If this is an entirely new indication, how this drug was considered for this should be discussed. Relevant information regarding pharmacological, toxicological and other biological properties of the drug/ biologic/ medical device, and previous efficacy and safety experience should be described.
2. Study Rationale
   This section should describe a brief summary of the background information relevant to the study design and protocol methodology. The reasons for performing this study in the particular population included by the protocol should be provided.
3. Study Objective(s) (primary as well as secondary) and their logical relation to the study design.
4. Study Design
   a. Overview of the Study Design: Including a description of the type of study (i.e., double-blind, multicentre, placebo controlled, etc.), a detail of the specific treatment groups and number of study Subjects in each group and investigative site, Subject number assignment, and the type, sequence and duration of study periods.
   b. Flow chart of the study
   c. A brief description of the methods and procedures to be used during the study.
   d. Discussion of Study Design: This discussion details the rationale for the design chosen for this study.
5. Study Population: the number of Subjects required to be enrolled in the study at the investiagative site and by all sites along with a brief description of the nature of the Subject population required is also mentioned.
6. Subject Eligibility
   a. Inclusion Criteria
   b. Exclusion Criteria
7. Study Assessments-plan, procedures and methods to be described in detail.
8. Study Conduct stating the types of study activities that would be included in this section would be: medical history, type of physical examination, blood or urine testing, electrocardiogram (ECG), diagnostic testing such as pulmonary function tests, symptom measurement, dispensation and retrieval of medication, Subject cohort assignment, adverse event review, etc.
   Each visit should be described separately as Visit 1, Visit 2, etc.
   Discontinued Subjects: Describes the circumstances for Subject withdrawal, dropouts, or other reasons for discontinuation of Subjects State how drop outs would be managed and if they would be replaced Describe the method of handling of protocol waivers, if any. The person(s) who approves all such waivers should be identified and the criteria used for specific waivers should be provided.
   Describes how protocol violations will be treated, including conditions where the study will be terminated for non-compliance with the protocol.
9. Study Treatment
   a. Dosing schedule (dose, frequency, and duration of the experimental treatment) Describe the administration of placebos and/ or dummy medications if they are part of the treatment plan. If applicable, concomitant drug(s), their doses, frequency, and duration of concomitant treatment should be stated.
   b. Study drug supplies and administration: A statement about who is going to provide the study medication and that the investigational drug formulation has been manufactured following all regulations Details of the product stability, storage requirements and dispensing requirements should be provided.
   c. Dose modification for study drug toxicity: Rules for changing the dose or stopping the study drug should be provided.
   d. Possible drug interactions

e. Concomitant therapy: The drugs that are permitted during the study and the conditions under which they may be used are detailed here.
Describe the drugs that a Subject is not allowed to use during parts of or the entire study. If any washout periods for prohibited medications are needed prior to enrollments, these should be described here.

f. Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the investigator and/ or the Subject

g. Unblinding procedures: If the study is blinded, the circumstances in which unblinding may be done and the mechanism to be used for unblinding should be given.

10. Adverse Events (See Appendix XI): Description of expected adverse events should be given. Procedures used to evaluate an adverse event should be described.

11. Ethical Considerations: Give the summary of:
a. Risk/ benefit assessment:
b. Ethics Committee review and communications
c. Informed consent process
d. Statement of Subject confidentiality including ownership of data and coding procedures

12. Study Monitoring and Supervision: A description of study monitoring policies and procedures should be provided along with the proposed frequency of site monitoring visits, and who is expected to perform monitoring.

Case Record Form (CRF) completion requirements, including who gets which copies of the forms and any specifics required in filling out the forms CRF correction requirements, including who is authorized to make corrections on the CRF and how queries about study data are handled and how errors, if any, are to be corrected should be stated.

Investigator study files, including what needs to be stored following study completion should be described.

13. Investigational Product Management
a. Give Investigational product description and packaging (stating all lingredients and the formulation of the investigational drug and any placebos used in the study)
b. The precise dosing required during the study.
c. Method of packaging, labeling, and blinding of study substances
d. Method of assigning treatments to Subjects and the Subject identification code numbering system.
e. Storage conditions for study substances.
f. Investigational product accountability: Describe instructions for the receipt, storage, dispensation, and return of the investigational products to ensure a complete accounting of all investigational products received, dispensed, and returned/ destroyed.
g. Describe policy and procedure for handling unused investigational products.

14. Data Analysis:
Provide details of the statistical approach to be followed including sample size, how the sample size was determined, including assumptions made in making this determination, efficacy endpoints (primary as well as secondary) and safety endpoints.
Statistical analysis: Give complete details of how the results will be analyzed and reported along with the description of statistical tests to be used to analyze the primary and secondary endpoints defined above. Describe the level of significanace, statistical tests to be used, and the methods used for missing data; method of evaluation of the data for treatment failures, non-compliance, and Subject withdrawals; rationale and conditions for any interim analysis if planned.
Describe statistical considerations for Pharmacokinetic (PK) analysis, if applicable.

15. Undertaking by the Investigator (see Appendix VII)

16. Appendices: Provide a study synopsis, copies of the informed consent documents (patient information sheet, informed consent form etc.); CRF and other data collection forms; a summary of relevant pre-clinical safety information and any other documents referenced in the clinical protocol.

APPENDIX-XI

Data Elements for reporting serious adverse events occuring in a clinical trial

1, Patient Details.
Initials & other relevant identifier (hospital/ OPD record number etc.)*

Gender
Age and/ or date of birth
Weight
Height

2. Suspectea Drug(s)
Generic name of the drug*
Indication(s) for which suspect drug was prescribed or tested
Dosage form and strength
Daily dose and regimen (specify units-e.g., mg, ml, mg/kg)
Route of administration
Starting date and time of day
Stopping date and time, or duration of treatment.

3. Other Treatment(s)
Provide the same information for concomitant drugs (including non prescription/ OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Suspected Adverse Drug Reaction(s)
Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.*
Start date (and time) of onset of reaction
Stop date (and time) or duration of reaction
Dechallenge and reachallenge information
Setting (e.g., hospital, out-patient clinic, home, nursing home)

5. Outcome
Information on recovery and any sequelae; results of specific tests and/ or treatment that may have conducted For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post-mortem findings.
Other intormation: anything relevant to tacilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

6. Details about the Investigator*
Name
Address
Telephone number
Profession (speciality)
Date of reporting the event to Licensing Authority:
Date of reporting the event to Ethics Committee overseeing the site:

Signature of the Investigator
Note: Information marked *must be provided."

[F.No. X-11014/1/2003-DMS & PFA]
RITA TEOTIA, Jt. Secy.

Foot Note: The Principal Rules were published in the Official Gazette vide notification No. F.28-10/45-H(i), dated the 21st December, 1945 and last amended vide G.S.R. 810(E) Dated 13.12.2004.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,
ರಿಚಾರ್ಡ್ ಲೋಬೋ
ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ
ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,
ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 104

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 104 ಕೇನಿಪ್ರ, 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 18ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಫೆಬ್ರವರಿ 22ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.237(E) [No. TC-I/2001/223/`1/pt.C] ದಿನಾಂಕ: 22.02.2005ನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF RAILWAYS
(Railway Board)
NOTIFICATION
New Delhi, the 21st February, 2005

S.O.237(E): In exercise of the powers conferred by Sub-section (1) of Section 89 of the Railways Act, 1989 (No. 24 of 1989), the Central Government, being satisfied that it is necessary that the goods booked by trains intended solely for the carriage of goods to any Railway Station should be removed without delay from such Railway Station and having regard to the factors specified in the first proviso to that sub-section hereby declares the following Railway Stations as 'Notified Stations' for the purpose of removal of goods without delay from such Stations for a period of six months with effect from 25.02.2005 namely:

Central Railway

1.	Ahmednagar	2.	Akola
3.	Amravati	4.	ambernath Goods Shed
179.	Quilon (B.G. Goods)	180.	Royapuram
181.	Salem Jn.	182.	Salem Market (B.G.)
183.	Trichur	184.	Tiruchirapalli Goods (B.G. & M.G.)
185.	Trivandrum Central (PO)	186.	Virudhunagar (B.G.)
	South Central Railway		
187.	Jadcherla	188.	Karimnagar
189.	Kurnool Town	190.	Mahabubnagar
191.	Nizamabad	192.	Reddipalem Goods Shed
	South Eastern Railway		
193.	Abada / SGTY	194.	Adra
195.	Balasore	196.	Bankura
197.	Bhaga Station (Bhaga Goods Shed)	198.	Bishnupur
199.	Bokaro Steel City	200.	Burnpur
201.	Chaibasa (Goods)	202.	Chakradharpur
203.	Chandrakona Road	204.	Dongaposi
205.	Jhargram	206.	Jharsuguda
207.	Hatia	208.	Kalaikunda
209.	Kharagpur	210.	Midnapur
211.	Muri	212.	Panskura
213.	Purulia	214.	Rourkela
215.	Rupsa	216.	Shalimar
217.	Soro	218.	Tatanagar
219.	Tatisilvai		
	South East Central Railway		
220.	Akaltara	221.	Amgaon
222.	Baradwar	223.	Belha
224.	Bhatapara	225.	Bilaspur
226.	Bishrampur	227.	Champa
228.	Chandia Road	229.	Chhindwara
230.	Dongargarh	231.	Durg
232.	Gondia	233.	Raipur Store Depot (RSD)
234.	Raipur	235.	Ramtake
236.	Rupaund	237.	Rajnandgaon
238.	Raigarh	239.	Shahdol
240.	Tilda	241.	Tirodi
242.	Umaria	243.	Usalapur
	South Western Railway		
244.	Baiyappanahalli	245.	Bangalore City (Parcel)
246.	Belgaum	247.	Bellary

248.	Bijapur	249.	Davangere
250.	Gadag	251.	Hospet
252.	Hubli (Goods)	253.	Hubli (Parcel)
254.	Koppal	255.	Mysore
256.	New Mysore Goods Terminal	257.	Sanvordam (Kudachere)
258.	Sattellite Goods Terminal /White Field	259.	Shimoga Town
260.	Tinaighat		
	Western Railway		
261.	Ahmedabad (BG & MG) Parcel	262.	Anand
263.	Ankleshwar	264.	Bandra Terminus (luggage)
265.	Bharuch	266.	Bhavnagar Terminus
267.	Bhimasar	268	Chittaurgarh
269.	Dahod	270.	Dewas
271.	Gandhidham	272.	Godhra
273.	Hapa	274.	Indore (B.G.) (Parcel)
275.	Indore (M.G.) (Goods & Parcel)	276.	Jogeshwari AT (Goods)
277.	Junagadh	278.	Kandla Port
279.	Kankariya	280.	Laksmibai Nagar (Goods)
281.	Mumbai Central (Luggage)	282.	Mundra Port Terminal
283.	Nadiad	284.	Nagda (Parcel)
285.	Parcel Depot Grant Road	286.	Rajkot
287.	Ranoli (Goods)	288.	Rathlam (B.G. & M.G.) (Parcel)
289.	Surat (Goods & Parcel)	290.	Ujjain
291.	Vadodara Jn. (Parcel) & Vadodara marshalling Yard (Goods)	292.	Viramgam
293.	Windmill		
	West Central Railway		
294.	Bhopal	295.	Kachhpura
296.	Satna	297.	Kota
298.	Katni-Murwara (Goods Shed)		

[No. TC-I/2001/223/I Pt.C]

SHIV KUMAR CHOWDHRI, Executive director, Traffic Commercial (Rates) Railway Board.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 110

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 106 ಕೇಶಾಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 18ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಫೆಬ್ರವರಿ 25ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.263(E) (No.F.No.8-5/2004/PP.I(pt)] ದಿನಾಂಕ: 25.02.2005 ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF AGRICULTURE

(Department of Agriculture and Cooperation)

NOTIFICATION

New Delhi, the 25th February, 2005

S.O.263(E): In exercise of the powers conferred by sub-section (1) of section 3 of the Destructive Insects and Pests Act, 1914 (2 of 1914), the Central Government hereby makes the following Order further to amend the Plant Quarantine (Regulation of Import into India) Order, 2003, namely:

1. (1) This Order may be called the Plant Quarantine (Regulation of Import into India) (second Amendment) Order, 2005.

(2) It shall come into force immediately on the expiry of ninety days from the date of its publication in the Official Gazette.

2. In Schedule VI attached to the Plant Quarantine (Regulation of Import into India) Order, 2005,-

(i) against serial number 19, in column (4), for the existing entry, the following entry shall be substituted, namely:
"Free from-
(a) Fusarial wilts (Fusarium oxysporum f.sp. cucumerinum)
(b) Black spot (Phomopsis sclerotoides)
(c) Septoria leaf spot (Septoria cucurbitarum)
(d) Cucumber seed-borne virus viz. leaf spot
(e) Verticillium albo-atrum
(f) squash mosaic virus."

(ii) against serial number 22, in column (4), against the entry "grape" occurring in column (3),-
(a) the existing items "(i) China, (ii), France, (iii) Iran, (iv) Italy, (v) New Zealand, (vi) South Africa and (vii) USA" shall be renumbered as items "(i) France, (ii) Iran, (iii) Italy, (iv) China, (v) New Zealand, (vi) South Africa and (vii) USA;
(b) under the entry "(ii) France", after item (e), the following item shall be inserted, namely:
("f) Lobesia botrana (grape berry moth)";
(c) Under the entry "(iii) Iran", after item (a), the following item shall be inserted, namely:
"(b) Lobesia botrana (grape berry moth)";
(d) under the entry "(iv) Italy", after item (g), the following item shall be inserted, namely:
"(h) Lobesia botrana (grape berry moth)";

(iii) against serial number 25, in column (4),
(a) for the item "(i) Maize viruses", the following item shall be substituted, namely:
"(i) Mycospharella zeae-maydis.";
(b) after entry (i), the following entries shall be inserted, namely:
"(j) Burkholderia andropogonis
(k) Pantoea agglomerans
(l) Pseundomonas fuscaviginae
(m) Pseudomonas syringae pv. coronofaciens
(n) Maize chlorotic dwarf machlovirus.";

(iv) against serial number 31, in column (4), for item (b), the following items shall be substituted, namely:
"(b) Pepper viruses viz. mild mosaic, mild mottle
(c) Peronospora hyoscyami sp. tabacina
(d) tomato ring spot virus
(e) tomato black ring virus."

(v) against serial number 39, in column (5), against entry (iii) relating to Stone fruit (fresh fruits for consumption), the following entries shall be inserted, namely:
"(a) Pest free area status for Mediterranean fruit fly (Ceraritis capitata) and Cherry fruit flies (Rhagoletis spp) as per international standards;
(b) MB fumigation @ 2 gm/m^3 for 2 hrs at 21^0C or above at NAP or equivalent thereof against cherry fruit flies and Mediterranean fruit fly; or
(c) Pre-shipment cold treatment at 0^0C or below for 10 days; 0.55^0C or below for 11 days; 1.1^0C or below for 12 days plus in-transit refrigeration against cherry fruit flies and Mediterranean fruit fly"

(vi) against serial number 43, in column (4), after item (d), the following items shall be inserted, namely:
"(e) Peronospora hyoscyami sp. tabacina
(f) Phoma andigena
(g) Verticillium albo-atrum
(h) Clavibacter michiganensis sub. sp. sepodonicus
(i) pepino mosaic virus
(j) tomato aspermy virus
(k) tomato black ring virus

(l) tomato bushy stunt virus
(m) tomato ring spot virus.";

(vii) against serial number 44, in column (4), against item (i), relating to seeds for sowing, mentioned in column (3), after item (d), the following items shall be inserted, namely:
"(e) Verticillium albo-atrum
(f) squash mosaic virus."

(ix) after serial number 341 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely:

Sl. No.	Plant Species	Category of Plant Material	Country of Origin	Additional Declarations required to be incorporated into Phytosanitary Certificate	Special Conditions of Import
1	2	3	4	5	6
"342.	Aphelandra squarrosa	Plants for propagation	USA	Free From Phytonemus pallidus (strawberry mite)	Post-entry quarantine growing for a period of 45 days.
343.	Cabbage, Cauliflower, Kohlrabi, Brussels sprouts, Broccoli, Knol Khol, Chinese Cabbage and other Cole crops (Brassica spp.)	(i) Seeds for sowing	(i) Netherlands, France China P.R., Korea, DPR Korea ROK, Thailand, Japan, USA, Taiwan, Australia, New Zeland	Free from: (a) Leptosphaeria maculans (black leg) (b) Pseudomonas viridiflava (bacterial leaf blight of tomato) (c) Pseudomonas syringae pv. maculicola (bacterial beaf spot) (d) Xanthomonas campestris pv. Campestris (black rot)	Freedom from soil and quarantine weed seeds.
			(ii) Denmark (iii) Italy	Nil	Freedom from soil and quarantine weeds seeds.
344.	Firwood (Abies spp.)	(i) Wood with bark	(i) Europe (except Portugal)	Free from: (a) Ips typographus (Spruce bark beetle) (b) Pityogenes chalcographus (Bark beetle, six dentated) (c) Tomicus piniperda (Beetle, pine)	Fumigation with Methyl bromide at 48g. per cubic metre for 24 hrs. at 21^0C and above or equivalent thereof or any other treatment approved by Plant Protection Adviser to the Government of India. The treatment should be endorsed on Phytosanitary Certificate issued at the country of origin/ re-export.

1	2	3	4	5	6
		(ii) Wood without bark	(ii) North America	Free from: (a) Dendrocatonus rufipennis (Spruce beetle) (b) Dioryctria abietivorella (Fir coneworm) (c) Dryocoetes confuses (Western balsam bark beetle) (d) Pityokteines sparsus (Balsam fir bark beetle) (e) Polygraphus rufipennis (Foureyed spruce bark beetle) (f) Tomicus piniperda (Beetle, pine) (g) Bursaphenchus xylophilus (Pine wood nematode)	Fumigation with Methyl bromide at 48g. per cubic metre for 24 hrs. at 21^{0}C and above or equivalent thereof or heat treatment at 56^{0}C (core temperature) for 30 minutes or any other treatment approved by Plant Protection Adviser to the Government of India. The treatment should be endorsed on Phytosanitary Certificate issued at the country of origin/ re-export.
345.	Kiwi (Actinidia chinensis & A. deliciosa)	(i) Fruits for consum ption	(i) Italy	Free from: (a) Aspidiotus nerii (aucuba scale) (b) Ceratitis capitata (Mediterranean fruit fly) (c) Pseudomonas syringae pv. Actinidiae (bacterial canker of kiwifruit) (d) Pseudomonas viridiflava (bacterial leaf blight of tomato (USA)	(i) Pest-free area status for Ceratitis capitata (Mediterranean fruit fly) as per international standards or (ii) MB fumigation @ 32 gm/m3 for $3^{1}/_{2}$ hrs at 21^{0}C or above or equivalent thereof or (iii) Pre-shipment cold treatment at 0^{0}C or below for 13 days; 0.55^{0}C or below for 14 days; 1.1^{0}C or below for 18 days plus in-transit refrigeration against Mediterranean fruit fly.
			(ii) Iran	Free from: (a) Aspidiotus nerii (aucuba scale) (b) Pseudomonas viridiflava (bacterial leaf blight of tomato (USA)	Nil

1	2	3	4	5	6
346.	Safflower (Carthamus tinctorius)	(i) Seeds for sowing	(i) Germany	Free from Pseudomonas viridiflava (Bacterial leaf blight of tomato (USA)	(i) imports permitted subject to prior approval of Department of Agriculture and Cooperation. (ii) Freedom from soil and quarantine weeds seeds.
		(ii) Grains (seeds) for consum ption	(ii) Australia, Mexico and Argentina	Nil	Devitalization of seed at the country of origin prior to export and the particulars of treatment to be endorsed on Phytosanitory certificate.
347.	Willows (Salix spp)	Wooden logs with bark/ clefts	Europe	Free from: (a) Saperda carcharias (greater poplar longhorn) (b) Saperda populnea (poplar borer) (c) zeuzera pyrina (wood leopard moth)	(i) Fumigation with Methyl bromide at 48g per cubic metre for 24 hrs. at 21^0C and above or equivalent there of or heat treatment at 56^0C for 30 minutes or any other treatment approved by the Plant Protection Adviser to the Government of India. The treatment should be endorsed on Phytosanitary Certificate issued at the Country of Origin/ re-export. Freedom from quarantine weeds seeds.

[F.No.8-5/2004-PP.I (Pt.)

ASHISH BAHUGUNA, Jt. Secy.

Note: The Plant Quarantine (Regulation of import into India) Order, 2003 was published in the Gazette of India vide S.O. 1322(E) dated 18th November, 2003, subsequently amended vide S.O.167(E) dated 06.02.2004, S.O. 427(E), dated 29th March, 2004 and S.O.644(E) dated 31.05.2004,_______________

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 111

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 105 ಕೇಶಾಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 18ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಡಿಸೆಂಬರ್ 23ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.247(E) [No.F.No.468/5/2005-Cus-V] ದಿನಾಂಕ: 23.02.2005 ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF FINANCE
(Department of Revenue)
CENTRAL BOARD OF EXCISE AND CUSTOMS)
New Delhi, the 23rd February, 2005
NOTIFICATION
No.18/2005 (N.T.)-CUSTOMS

S.O.263(E): In exercise of the powers conferred by sub-clause (i) of clause (a) of Sub-section (3) of Section 14 of Customs Act, 1962 (52 of 1962) and in supersession of the notification of the Government of India in the Ministry of Finance (Department of Revenue) No.10/2005 (NT)-Customs, dated the 25th January, 2005 [S.O. 84(E), dated the 25th January, 2005], the Board hereby determines for the purposes of said section relating to export goods, that the rate of exchange of conversion of each of the foreign currency specified in column (2) of each of Schedule-I and Schedule-II appended hereto into Indian currency or vice versa shall, with effect from the 1st March, 2005, be the rate mentioned against it in the corresponding entry in column (3) thereof.

SCHEDULE-I

Sl. No.	Foreign Currency	Rate of exchange of one unit of Foreign Currency equivalent to Indian Rupees
1	2	3
1.	Australian Dollar	34.40
2.	Canadian Dollar	35.40
3.	Danish Kroner	7.70
4.	EURO	57.25
5.	Hong Kong Dollar	5.60
6.	Norwegian Kroner	6.90
7.	Pound Sterling	82.90
8.	Swedish Kroner	6.30
9.	Swiss Franc	37.05
10.	Singapore Dollar	26.65
11.	US Dollar	43.60

SCHEDULE-II

Sl. No.	Foreign Currency	Rate of exchange of 100 units of Foreign Currency equivalent to Indian Rupees
1	2	3
1.	Japanese Yen	41.45

[F.No.468/5/2005-Cus.V]

S.P. RAO, Under Secy.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 112

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 112 ಕೇಶಾಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 18ನೇ ಏಪ್ರಿಲ್, 2005

2004ನೇ ಸಾಲಿನ ಡಿಸೆಂಬರ್ 28ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.1419(E) [No.F.No.468/17/2004-Cus-V] ದಿನಾಂಕ: 28.12.2004 ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF FINANCE
(Department of Revenue)
(CENTRAL BOARD OF EXCISE AND CUSTOMS)
New Delhi, the 28th December, 2004
NOTIFICATION
No.148/2004 (NT)-CUSTOMS

S.O.1419(E): In exercise of the powers conferred by sub-clause (i) of clause (a) of Sub-section (3) of Section 14 of Customs Act, 1962 (52 of 1962) and in supersession of the notification of the Government of India in the Ministry of Finance (Department of Revenue) No.129/2004 (NT)-Customs, dated the 24th November, 2004 [S.O.1298(E), dated the 24th November, 2004], the Board hereby determines for the purposes of said section relating to imported goods, that the rate of exchange of conversion of each of the foreign currency specified in column (2) of each of Schedule-I and Schedule-II appended hereto into Indian currency or vice versa shall, with effect from the 1st January, 2005, be the rate mentioned against it in the corresponding entry in column (3) thereof.

SCHEDULE-I

Sl. No.	Foreign Currency	Rate of exchange of one unit of Foreign Currency equivalent to Indian Rupees
1	2	3
1.	Australian Dollar	34.00
2.	Canadian Dollar	35.85
3.	Danish Kroner	8.00
4.	EURO	59.65
5.	Hong Kong Dollar	5.65
6.	Norwegian Kroner	7.20
7.	Pound Sterling	84.80
8.	Swedish Kroner	6.60
9.	Swiss Franc	38.60
10.	Singapore Dollar	26.80
11.	US Dollar	44.00

SCHEDULE-II

Sl. No.	Foreign Currency	Rate of exchange of 100 units of Foreign Currency equivalent to Indian Rupees
1	2	3
1.	Japanese Yen	42.55

[F.No.468/17/2004-Cus.V]
S.P. RAO, Under Secy.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,
ರಿಚಾರ್ಡ್ ಲೋಬೋ
ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ
ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,
ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 113

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 107 ಕೇಶಾಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 18ನೇ ಏಪ್ರಿಲ್, 2005

2005ನೇ ಸಾಲಿನ ಫೆಬ್ರವರಿ 23ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.248(E) [No.F.No.468/5/2005-Cus-V] ದಿನಾಂಕ: 23.02.2005 ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF FINANCE
(Department of Revenue)
CENTRAL BOARD OF EXCISE AND CUSTOMS)
New Delhi, the 23rd February, 2005
NOTIFICATION
No.17/2005 (N.T.)-CUSTOMS

S.O.248(E): In exercise of the powers conferred by sub-clause (i) of clause (a) of Sub-section (3) of Section 14 of Customs Act, 1962 (52 of 1962) and in supersession of the notification of the Government of India in the Ministry of Finance (Department of Revenue) No.9/2005 (NT)-Customs, dated the

25th January, 2005 [S.O.83(E), dated the 25th January, 2005], the Board hereby determines for the purposes of said section relating to imported goods, that the rate of exchange of conversion of each of the foreign currency specified in column (2) of each of Schedule-I and Schedule-II appended hereto into Indian currency or vice versa shall, with effect from the 1st January, 2005, be the rate mentioned against it in the corresponding entry in column (3) thereof.

SCHEDULE-I

Sl. No.	Foreign Currency	Rate of exchange of one unit of Foreign Currency equivalent to Indian Rupees
1	2	3
1.	Australian Dollar	34.75
2.	Canadian Dollar	35.75
3.	Danish Kroner	7.75
4.	EURO	57.75
5.	Hong Kong Dollar	5.65
6.	Norwegian Kroner	7.00
7.	Pound Sterling	83.65
8.	Swedish Kroner	6.35
9.	Swiss Franc	37.45
10.	Singapore Dollar	26.90
11.	US Dollar	43.90

SCHEDULE-II

Sl. No.	Foreign Currency	Rate of exchange of 100 units of Foreign Currency equivalent to Indian Rupees
1	2	3
1.	Japanese Yen	41.85

[F.No.468/5/2005-Cus.V]

S.P. RAO, Under Secy.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 114

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 113 ಕೇಶಾಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 18ನೇ ಏಪ್ರಿಲ್, 2005

2004ನೇ ಸಾಲಿನ ಡಿಸೆಂಬರ್ 28ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.1420(E) [No.F.No.468/17/2004-Cus-V] ದಿನಾಂಕ: 28.12.2004 ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF FINANCE
(Department of Revenue)
(CENTRAL BOARD OF EXCISE AND CUSTOMS)
New Delhi, the 28th December, 2004
NOTIFICATION
No.149/2004 (N.T.)-CUSTOMS

S.O.1420(E): In exercise of the powers conferred by sub-clause (i) of clause (a) of Sub-section (3) of Section 14 of Customs Act, 1962 (52 of 1962) and in supersession of the notification of the Government of India in the Ministry of Finance (Department of Revenue) No.130/2004 (NT)-Customs, dated the 24th November, 2004 [S.O.1299(E), dated the 24th November, 2004], the Board hereby determines for the purposes of said section relating to export goods, that the rate of exchange of conversion of each of the foreign currency specified in column (2) of each of Schedule-I and Schedule-II appended hereto into Indian currency or vice versa shall, with effect from the 1st January, 2005, be the rate mentioned against it in the corresponding entry in column (3) thereof.

SCHEDULE-I

Sl. No.	Foreign Currency	Rate of exchange of one unit of Foreign Currency equivalent to Indian Rupees
1	2	3
1.	Australian Dollar	33.65
2.	Canadian Dollar	35.55
3.	Danish Kroner	7.95
4.	EURO	59.10
5.	Hong Kong Dollar	5.60
6.	Norwegian Kroner	7.15
7.	Pound Sterling	84.00
8.	Swedish Kroner	6.55
9.	Swiss Franc	38.20
10.	Singapore Dollar	26.55
11.	US Dollar	43.65

SCHEDULE-II

Sl. No.	Foreign Currency	Rate of exchange of 100 units of Foreign Currency equivalent to Indian Rupees
1	2	3
1.	Japanese Yen	42.15

[F.No.468/17/2004-Cus.V]

S.P. RAO, Under Secy.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 115

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 114 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 18ನೇ ಏಪ್ರಿಲ್, 2005

2004ನೇ ಸಾಲಿನ ಡಿಸೆಂಬರ್ 20ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.1395(E) [No.F.No.NH-11014/2/2004-P&M] ದಿನಾಂಕ: 20.12.2004 ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF SHIPPING, ROAD TRANSPORT AND HIGHWAYS

(Department of Road Transport and Highways)

NOTIFICATION

New Delhi, the 20th December, 2004

S.O.1395(E): In exercise of the powers conferred by Sub-sections (1) and (2) of Section 5 of the Control of National Highways (Land and Traffic) Act, 2002 (13 of 2003) the Central Government hereby establishes the National Highways Tribunals mentioned in Column (2) of the Table given below at the respective places mentioned against each in column (3) of the said Table with the limits of the National Highways shown against each in the corresponding column (4) of the said Table within which the respective Tribunal shall exercise its jurisdiction, powers and authority:

TABLE

Serial Number	Name of National Highways Tribunal	Place of location of Tribunal	Limits of the National Highways within the jurisdiction of the Tribunal
1	2	3	4
6.	National Highways Tribunal, Bangalore.	Bangalore	All the lengths of National Highways within local limits of States of the Kerala and Karnataka.

2. This notification shall come into force on the date on which the Control of National Highways (Land and Traffic) Act, 2002 (13 of 2003) shall come into force.

[F.No.NH-11014/2/2004-P & M]

ALOK RAWAT. Jt. Secy.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಪಿ.ಆರ್. 116 ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 117 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 18ನೇ ಏಪ್ರಿಲ್, 2005

2004ನೇ ಸಾಲಿನ ಡಿಸೆಂಬರ್ 27ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(i)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.838(E) [No.F.No.2/17/2004-NS.II] ದಿನಾಂಕ: 27.12.2004 ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF FINANCE

(Department of Economic Affairs)

NOTIFICATION

New Delhi, the 27th December, 2004

G.S.R.838 (E): In exercise of the powers conferred by Section 15 of the Government Savings Banks Act, 1873 (5 of 1873), the Central Government hereby makes the following rules further to amend the Post Office Recurring Deposit Rules, 1981, namely:

1. (1) These rules may be called the Post Office Recurring Deposit (Amendment) rules, 2004.
   (2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Post Office Recurring Deposit Rules, 1981, in rule 14, in sub-rule (3), after item (e), the following item shall be inserted, namely:

"(f) For withdrawals made on or after 1st January, 2005 — 2 percent, over and above the interest rate applicable to the deposits made for a period of five years under the Post Office Time Deposit Rules, 1981, on the date of withdrawal.".

[F.No.2/17/2004-NS.II]

P.C. SINGH, Under Secy.

Note: The principal rules were published vide GSR 666(E) dated 17th December, 1981 and amended vide GSR 301(E) dated 1st April, 1982, GSR 258(E) dated 11th March, 1983, GSR 62(E) dated 14th February, 1984, GSR 95(E) dated 7th February, 1986, GSR 194(E) dated 13th February, 1986, GSR 363(E) dated 1st April, 1987, GSR 39(E) dated 16th January, 1988, GSR 458(E) dated 15th April, 1988, GSR 708(E) dated 21st July, 1989, GSR 16(E) dated 9th January, 1990, GSR 190(E) dated 27th March, 1991, GSR 579(E) dated 12th September, 1991, GSR 918(E) dated 11th December, 1992, GSR 42(E) dated 1st February, 1993, GSR 587(E) dated 2nd September, 1993, GSR 2(E) dated 1st January, 1999, GSR 748(E) dated 4th November, 1999, GSR 44(E) dated 15th January, 2000, GSR 152(E) dated 1st March, 2001, GSR 160(E) dated 1st March, 2002, GSR 514(E) dated 23rd July, 2002, GSR 662(E) dated 23rd September, 2002, GSR 175(E) dated 1st March, 2003 and GSR 588(E) dated 25th July, 2003.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ರಿಚಾರ್ಡ್ ಲೋಬೋ

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಪಿ.ಆರ್. 119 ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 115 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 18ನೇ ಏಪ್ರಿಲ್, 2005

2004ನೇ ಸಾಲಿನ ಡಿಸೆಂಬರ್ 28ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(ii)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ S.O.1418(E) [No.F.No.14/3/2003-PP&C] ದಿನಾಂಕ: 28.12.2004 ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF COMMERCE AND INDUSTRY

(Department of Industrial Policy and Promotion)

NOTIFICATION

New Delhi, the 28th December, 2004

S.O.1418 (E): WHEREAS, the Central Government in exercise of the powers conferred by Section 159 of the Patents Act, 1970 (39 of 1970) framed the Patents Rules, 2003;

AND WHEREAS, the Central Government has decided to amend the Patents Act, 1970;

AND WHEREAS, in view of the above, it has become necessary to update the Patents Rules, 2003 on the lines contained in the amendments to the Patents Act, 1970;

AND WHEREAS, the proviso to sub-section (3) of section 159 of the Patents Act, 1970 as amended by the Patents (Amendment) Ordinance 2004, empowers the Central Government to dispense with the requirement of previous publication of rules as required under the said sub-section (3) of section 159;

AND WHEREAS, the Central Government is satisfied that circumstances exist which render it practically not possible to comply with the condition of previous publication;

AND WHEREAS, the Central Government has decided to dispense with the requirement of previous publication of the following amendment rules required to be made under section 159 of the said Act;

NOW, THEREFORE, in exercise of the powers conferred by section 159 of the Patents Act, 1970, the Central Government hereby makes the following rules to amend the Patents Rules, 2003, namely:

1. (1) These rules may be called the Patents (Amendment) Rules, 2005.
   (2) They shall come into force on the 1st January, 2005.
2. In the Patents Rules, 2003 (hereinafter referred to as the principal rules), in rule 4, in sub-rule (1), in clauses (i) and (ii) and (ii), the figures and letters "24A, 24B and 24C" occurring at both the places shall be omitted.
3. In rule 5 of the principal rules, after the words "the Act or these rules", occurring at the end, the words "and the Controller may take suo-moto decision in the matter" shall be added.
4. In rule 6 of the principal rules, for sub-rule (1), the following sub-rule shall be substituted, namely:
   "(1) Any application, notice or other document authorized or required to be filed, left, made or given at the patent office, or to the Controller or to any other person under the Act or these rules, may be tendered by hand or sent by a letter addressed to the Controller at the appropriate office or to that person through post or registered post or speed post or courier service or by electronic transmission duly authenticated. If it is sent by post or registered post or speed post or courier service or by electronic transmission duly authenticated, it shall be deemed to have been filed, left, made or given at the time when the mail containing the same would have been delivered in the ordinary course of post or registered post or speed post or courier service, or by electronic transmission duly authenticated, as the case may be. In proving such sending, it shall be sufficient to show that the mail was properly addressed and transmitted:
   Provided that any application, notice or the document sent through fax or by electronic transmission duly authenticated, shall also be deemed to have been filed, left, made or given if the same is clear and fully legible and its original or paper copy, as the case may be, is submitted to the appropriate office within one month from the date of receipt of the such fax or by electronic transmission duly authenticated.".
5. In rule 7 of the principal rules, for sub-rule (4), the following sub-rule shall be substituted, namely:
   "(4) Fees once paid in respect of any proceeding shall not ordinarily be refunded irrespective of whether the proceeding has taken place or not.".
6. In rule 12 of the principal rules,-
   (a) after sub-rule (1), the following sub-rule shall be inserted, namely:

"(1A). The period within which the applicant shall file the statement and undertaking under sub-section (1) of section 8 shall be three months from the date of filing the application.

Explanation- For the purpose of this rule, the period of three months in case of an application corresponding to an international application in which India is designated shall be reckoned from the actual date on which the corresponding application is filed in India.".

(b) for sub-rules (3) and (4), the following sub-rule shall be substituted, namely:

"(3) When so required by the Controller under sub-section (2) of section 8, the applicant shall furnish information relating to objections, if any, in respect of novelty and patentability of the invention and any other particulars as the Controller may require which may include claims of application allowed within three months from the date of such communication by the Controller.".

7. In rule 13 of the principal rules,-

(a) for sub-rule (6), the following sub-rule shall be substituted, namely:

"(6) Except in the case of an application (other than a convention application or an application filed under the Patent Cooperation Treaty designating India) which is accompanied by a complete specification, a declaration as to the inventorship of the invention shall be filed in Form 5 with the complete specification or at any time before the expiration of one month from the date of filing of the complete specification, as the Controller may allow on an application made in Form 4.".

(b) after sub-rule (7), the following sub-rule shall be inserted, namely:

"(8) The period within which reference to the deposit shall be made in the specification under sub-clause (A) of clause (ii) of sub-section (4) of section 10 shall be three months from the date of filing of the application.".

8. For rule 14 of the principal rules, the following rule shall be substituted, namely:

"14 **Amendments to specifications.-** (1) When a provisional or complete specification or any drawing accompanying it has been received by the applicant or his agent for amendment, and amendment is duly made thereon, the page incorporating such amendment shall be retyped and submitted to form a continuous document. Amendments shall not be made by slips pasted on, or as footnotes or by writing in the margin of any of the said documents.

(2) The amended documents shall be returned to the Controller together with the superseded pages or drawings, if any, duly marked, cancelled and initialed by the applicant or his agent. Copies of any pages that have been retyped or added and of any drawing that has been added or substantially amended shall be sent in duplicate.".

9. In rule 19 of the principal rules, for sub-rule (1), the following sub-rule shall be substituted, namely:

"(1) An international application shall be filed with the appropriate office in triplicate either in English or in Hindi language.".

10. In rule 20 of the principal rules,-

(a) in sub-rule (1) for the word, figure and letter "Form 1A", the word and figure "Form-1" shall be substituted.

(b) in sub-rules (2) and (3), for the words, bracket and figure, "sub-rule (4)", the words, bracket and figures "sub-rule (4)(i)" shall respectively be substituted.

(c) in sub-rule (3), in clause (b), after the words "duly verified by the applicant", the words "or the person duly authorized by him" shall be inserted.

(d) for sub-rule (4), the following sub-rule shall be substituted, namely:

"(4) (i) The time limit referred to in sub-rule (2) shall be thirty one months from the priority date as referred to in Article 2(xi);

(ii) Notwithstanding anything contained in clause (i), the Patent Office may, on the express request filed in Form-18 along with the fee specified in first schedule, process or examine the application at any time before thirty one months.".

11. In rule 21 of the principal rules, in sub-rule (2), after the words "duly verified by the applicant", the words "or the person duly authorized by him" shall be inserted.

12. For rule 24 of the principle rules, the following rules shall be substituted, namely:

"24. **Publication of application.-** The period for which an application for patent shall not ordinarily be open to public under sub-section (1) of section 11A shall be eighteen months from the date of filing of application or the date of priority of the application, whichever is earlier.

24A. Request for publication.- A request for publication under sub-section (2) of section 11A shall be made in Form 9.".

24B. Examination of application.- (1) (i) A request for examination under section 11B shall be made in Form 18 after the publication of the application but within thirty-six months from the date of priority of the application or from the date of filing of the application, whichever is earlier;

(ii) The period within which the request for examination under sub-section (3) of section 11B to be made shall be thirty-six months from the date of priority or from the date of filling of the application or twelve months from the 1st day of January, 2005;

(iii) The request for examination under sub-section (4) of section 11B shall be made after the publication of the application, but within thirty-six months from the date of priority or form the date of filing of the application, or within six months from the date of revocation of the secrecy direction, whichever is later;

(iv) The request for examination of application as filed according to the 'Explanation' under sub-section (3) of section 16 shall be made after the publication of the first mentioned application, but within thirty-six months from the date of filing of the application or from the date of priority of the first mentioned application or within six months from the date of filing of the further application, whichever is later;

(v) The period for making request for examination under section 11B, of the applications filed before the 1st day of January, 2005 shall be the period specified under the section 11B or the period specified under these rules, whichever expires later.

(2) (i) A request for examination of application for patent filed under sub-rule (1) shall be taken up for examination in the order in which the request is filed;

(ii) The period within which the examiner shall make the report under sub-section (2) of section 12, shall ordinarily be one month but not exceeding three months from the date of reference of the application to him by the Controller.

(3) A first examination report along with the application and specification shall be sent to the applicant or his authorized agent. In case other interested person files the request for examination, an intimation of such examination may be sent to such interested person.

(4) (i) The time for putting an application in order for grant under section 21 shall be six months from the date on which the first statement of objection is issued to the applicant to comply with the requirements;

(ii) Notwithstanding anything contained in these rules; the period specified in clause (i) may be extended for a further period not exceeding three months by the Controller in circumstances beyond the control of the applicant, on a request made in Form 4 by the applicant along with fee specified in the First Schedule before expiry of the time specified in clause (i);

(iii) The time for putting an application in order for grant which has been examined before the 1st day of January, 2005, shall be twelve months from the date on which the first statement of objections has been issued to the applicant to comply with the requirements.".

13. In rule 26 of the principal rules, sub-rule (2) shall be omitted.

14. For rule 27 of the principal rules, the following rule shall be substituted, namely:

"27. Inspection and supply of published documents: After the date of publication of the application under section 11A, the application together with the complete specification and provisional specification, if any, the drawing, if any, and the abstract filed in respect of the application may be inspected at the appropriate office by making a written request to the Controller on payment of the fee in that behalf and copies thereof may be obtained on payment of fees specified in the First Schedule.".

15. In rule 28 of the principal rules,
   (a) in sub-rule (2), in the first proviso, for the word "specified", the words "referred to" shall be substituted;
   (b) in sub-rule (5), for the words "accept the specification", the words "grant the patent" shall be substituted;
16. After rule 28 of the principal rules, the following rule shall be inserted, namely:
   "28A. Procedure in relation to consideration of report of examiner under section 14.- In case the applicant contests any of the objections communicated to him, the procedure specified under rule 28 may apply.".
17. In rule 29 of the principal rules, for sub-rule (2), the following sub-rule shall be substituted, namely:
   "(2) If the applicant's specification is otherwise in order for grant and an objection under clause (b) of sub-section (1) of section 13 is outstanding, the Controller may postpone the grant of patent and allow a period of two months for removing the objection.".
18. In rule 32 of the principal rules, the words and figures "or section 25" shall be omitted.
19. For rule 37 of the principal rules, the following rule shall be substituted, namely:
   "37. Numbering of applications on the grant of patent.- On the grant of a patent, the application shall be accorded a number (called serial number) in the series of numbers accorded to patents under the Indian Patents and Designs Act, 1911 (2 of 1911) which shall be the number of the patent so granted.".
20. Rule 38 of the principal rules shall be omitted.
21. In Chapter V of the principal rules, (rules 39 of 54) shall be omitted.
22. In Chapter VI of the principal rules, for the heading "OPPOSITION TO THE GRANT OF PATENT", the following heading shall be substituted, namely:
   "OPPOSITION PROCEEDINGS"
23. For rules 55 to 57 of the principal rules, the following rules shall be substituted, namely:
   "55. Opposition by representation against the grant of patent.- (1) Representation for opposition under sub-section (1) of section 25 shall be filed at the appropriate office within a period not exceeding three months from the date of publication of the application under section 11A of the Act, or before the grant of patent, whichever is later and shall include a statement and evidence, if any, in support of the representation and a request for hearing if so desired.
   (2) The Controller shall consider such representation only when a request for examination of the application has been filed.
   (3) On consideration of the representation if the Controller is of the opinion that application for patent shall be refused or the complete specification requires amendment, he shall give a notice to the applicant to that effect.
   (4) On receiving the notice under sub-rule (3), the applicant shall, if he so desires, file his statement and evidence, if any in support of his application within one month from the date of the notice.
   (5) On consideration of the statement and evidence filed by the applicant, the Controller may either refuse to grant a patent on the application or require the complete specification to be amended to his satisfaction before the patent is granted.
   (6) After considering the representation and submission made during the hearing if so requested, the Controller shall proceed further simultaneously either rejecting the representation and granting the patent or accepting the representation and refusing the grant of patent on that application, ordinarily within one month from the completion of above proceedings.

   55A. Filing of notice of opposition.- The notice of opposition to be given under sub-section (3) of section 25 shall be made in Form 7 and sent to the Controller in duplicate at the appropriate office.

   56. Constitution of Opposition Board and its proceeding.-
   (1) On receipt of notice of opposition, the Controller shall, by order, constitute an Opposition Board consisting of three members and nominate one of the members as the Chairman of the Board.
   (2) An examiner appointed under sub-section (2) of section 73 shall be eligible to be a member of the Opposition Board.

(3) The examiner, who has dealt with the application for patent during the proceeding for grant of patent thereon shall not be eligible as member of Opposition Board as specified in sub-rule (2) for that application.

(4) The Opposition Board shall conduct the examination of the notice of opposition along with documents filed under rules 57 to 60 referred to under sub-section (4) of section 25, submit a report with reasons on each ground taken in the notice of opposition with its joint recommendation within three months from the date on which the documents were forwarded to them.

57. Filing of written statement of opposition and evidence.- The opponent shall send a written statement in duplicate setting out the nature of the opponent's interest, the facts upon which he bases his case and relief which he seeks and evidence, if any, along with notice of opposition and shall deliver to the patentee a copy of the statement and the evidence, if any.".

24. In rule 58 of the principal rules,-

(a) in sub-rule (1), for the word "applicant", the word "patentee" shall be substituted;

(b) for sub-rule (2), the following sub-rule shall be substituted, namely:

"(2) If the patentee does not desire to contest or leave his reply and evidence within the period as specified in sub-rule (1), the patent shall be deemed to have been revoked.".

25. In rule 59 of the principal rules, for the word "applicant's wherever they occur, and for the word "applicant", the words "patentee's" and "patentee" shall respectively be substituted.

26. In rule 62 of the principal rules,-

(a) In Schedule (1), the following sub-rule shall be substituted, namely:

"(1) On the completion of the presentation of evidence, if any, and on receiving the recommendation of Opposition Board or at such other time as the Controller may think fit, he shall fix a date and time for the hearing of the opposition and shall give the parties not less than ten day's notice of such hearing and may require members of Opposition Board to be present in the hearing.".

(b) for sub-rule (5), the following sub-rule shall be substituted, namely:

"(5) After hearing the party or parties desirous of being heard, or if neither party desires to be heard, then without a hearing, and after taking into consideration the recommendation of Opposition Board, the Controller shall decide the opposition and notify his decision to the parties giving reasons therefore.".

27. For rule 63 of the principal rules, the following rule shall be substituted, namely:

"63. Determination of costs.- If the patentee notifies the Controller that he desires to withdraw the patent after notice of opposition is given, the Controller, depending on the merits of the case, may decide whether costs should be warded to the opponent.".

28. After rule 63 of the principal rules, the following rule shall be inserted, namely:

"63A. Request made under section 26(1).- Request under section 26(1) shall be made on Form 12 within three months from the date of the order of the Controller and shall be accompanied by a statement setting out the facts upon which the petitioner relies and relief he claims.".

29. Rules 64 and 65 of the principal rules shall be omitted.

30. For rule 69 of the principal rules, the following rule shall be substituted, namely:

"69. Procedure for the hearing of claim or an application under section 28.- The procedure specified in rules 55A and 57 to 63 relating to the filing of notice of opposition, written statement, reply statement, leaving evidence, hearing and cost shall, so far as may be, apply to the hearing of a claim or an application under section 28 as they apply to the opposition proceedings subject to the modification that reference to patentee shall be construed as the person making the claim, or an application, as the case may be.".

31. For rule 71 of the principal rules, the following rule shall be substituted, namely:

"71. Permission for making patent application outside India under section 39.- (1) The request for permission for making patent application outside India shall be made in Form 25.

(2) The request made under sub-rule (1) shall be disposed of by the Controller ordinarily within a period of three months from the date of filing of such request.".

32. In CHAPTER VIII, for the existing heading, the following heading shall be substituted, namely: "GRANT OF PATENTS".

33. Rule 73 of the principal rules shall be omitted.

34. After rule 74 of the principal rules, the following rule shall be inserted, namely:

"74A. Inspection of documents related to grant of patent.- After the date of publication of a grant of a patent, the application together with the complete specification and provisional specification, if any, the drawing if any, abstract and other documents related thereto may be inspected at the appropriate office by making a written request to the Controller and on payment of fee and may obtain copies on payment of fee specified in the First Schedule.".

35. For rule 78 of the principal rules, the following rule shall be substituted, namely:

"78. Procedure for the hearing of proceedings under section 51.- The procedure specified in rules 55A and 57 to 63 relating to the filing of notice of opposition, written statement, reply statement, leaving evidence, hearing and costs shall, so far as may be, apply to the hearing of an application under section 51 as they apply to the hearing of an opposition proceeding.".

36. In rule 79 of the principal rules, before the word "court" wherever it occurs, the words "Appellate Board or" shall be inserted.

37. In rule 80 of the principal rules, after sub-rule (1), the following sub-rule shall be inserted, namely:

"(1A) The period for payment of renewal fees so specified in sub-rule (1) may be extended to such period not being more than six months if the request for such extension of time is made in Form 4 with the fee specified in the First Schedule.".

38. In rule 81 of the principal rules,-

(a) in sub-rule (2), for the word "accepted", the word "granted" shall be substituted;

(b) for sub-rule (3), the following sub-rule shall be substituted, namely:

"3(a) If the application for amendment under sub-rule (1) is made after grant of patent and the nature of the proposed amendment is substantive, the application shall be published.

(b) Any person interested in opposing the application for amendment shall give a notice of opposition in Form 14 within three months from the date of publication of the application.

(c) The procedure specified in rules 57 to 63 relating to the filing of written statement, reply statement, leaving evidence, hearing and costs shall, so far as may be, apply to the hearing of the opposition under section 57 as they apply to the hearing of an opposition proceeding.".

39. For rule 83 of the principal rules, the following rules shall be substituted, namely:

"83. Publication of the amendment allowed.- The amendments allowed after a patent has been granted, shall be published.

40. In rule 84 of principal rules, for sub-rule (3), the following sub-rule shall be substituted, namely:

"(3) Where applicant requests for a hearing within the time allowed and the Controller, after giving the applicant such a hearing, is prima facie satisfied that the failure to pay the renewal fees was unintentional, he shall publish the application.".

41. For the 85 of the principal rules, the following rules shall be substituted, namely:

"85. Opposition to restoration under section 61.- (1) At any time, within two months from the date of publication of the application under sub-rule (3) of rule 84, any person interested may give notice of opposition thereto in Form 14.

(2) A copy of the notice of opposition shall be sent by the Controller to the applicant.

(3) The procedure specified in rules 57 to 63 relating to the filing of written statement, reply statement, leaving evidence, hearing and costs shall, so far as may be, apply to the hearing of the opposition under section 60 as they apply to the hearing in the opposition proceeding.".

42. In rule 86 of the principal rules, for sub-rule (2), the following sub-rule shall be substituted, namely:

"(2) The Controller shall publish his decision.".

43. For rule 87 of the principal rules, the following rules shall be substituted, namely:

"87. Surrender of Patents.- (1) The Controller shall publish the notice of an offer given under section 63.

(2) Any person interested may, within three months from the date of publication of the notice, give notice of opposition to the Controller in Form 14 in duplicate.

(3) The procedure specified in rules 57 to 63 relating to the filing of written statement, reply statement, leaving evidence, hearing and costs shall, so far as may be, apply to the hearing of the opposition under section 63 as they apply to the hearing in opposition proceeding.

(4) If the Controller accepts the patentee's offer to surrender the patent, he may direct the patentee to return the patent, and on receipt of such patent, the Controller shall by order revoke it and publish the revocation of the patent.".

44. In sub-rule (2) of rule 88 of the principal rules, for the words "Controller of the courts", the words "Controller or Appellate Board or the courts" shall be substituted.

45. Rule 89 of the principal rules shall be omitted.

46. In rule 90 of the principal rules, for the word and figures "Form 17 occurring at both the places, the word and figures "Form 16" shall be substituted.

47. For rule 96 of the principal rules, the following rules shall be substituted namely:

"96. Application for compulsory licence etc.- An application to the Controller for an order under section 84, section 85, section 91 or section 92 or section 92A shall be in Form 17, or Form 19, as the case may be. Except in the case of an application made by the Central Government, the application shall set out the nature of the applicant's interest and terms and conditions of the licence the applicant is willing to accept.".

48. In rule 98 of the principal rules,-

(a) in sub-rule (1), for the word "advertisement", the word "publication shall be substituted;

(b) in sub-rule (6), for the words "of opposition to the grant of patents", the words "in opposition proceedings" shall be substituted.

49. For rule 99 of the principal rules, the following rule shall be substituted, namely:

"99. Manner of publication of the revocation order.- The Controller shall publish the order made by him under sub-section (3) of section 85 revoking a patent.".

50. In rule 100 of the principal rules, for the word and figures "Form 21", the words and figures "Form 20" shall be substituted.

51. In rule 101 of the principal rules, in sub-rule (7), for the words "of opposition to the grant of patents", the words "in opposition proceedings" shall be substituted.

52. In rule 102 of the principal rules,-

(a) in sub-rule (1), for the word and figures "Form 22", the word and figures "Form 21" shall be substituted;

(b) in sub-rule (6), for the words "of opposition to the grant of a patent", the words "in opposition proceeding." shall be substituted.

53. In rule 103 of the principal rules, in sub-rule (1), for the words "names and addresses", the words "names, addresses, specimen signatures and photographs" shall be substituted.

54. In rule 108 of the principal rules, after sub-rule (2), the following sub-rule shall be inserted, namely:

"(3) (i) Copies of register of patent agents shall be maintained in each of the branch offices;

(ii) The register of patent agents shall also contain specimen signatures and photographs of the persons registered as patent agents.".

55. In rule 109 of the principal rules, in sub-rule (1), for the word and figures "Form 23", the word and figures "Form 22" shall be substituted.

56. In rule 110 of the principal rules, for sub-rule (3), the following sub-rule shall be substituted, namely:

"(3) The qualifying marks for each written paper and for the viva voce examination shall be fifty percent each, of total marks and a candidate shall be declared to have passed the examination only if he obtaining an aggregate of sixty percent of the total marks.".

57. After rule 111 of the principal rules, the following rule shall be inserted namely:

"111A- Issue of duplicate certificate of patent agents.- The Controller may issue a duplicate certificate of registration as patent agent on a request made by the person so registered as patent agent along with fee specified in the first schedule and contain a statement setting out the circumstances in which the original certificate issued under rule 111 was lost, destroyed and can not be produced.".

58. In rule 112 of the principal rules, for the word and figures "Form 23", the word and figures "Form 22" shall be substituted.

59. In rule 116 of the principal rules, in sub-rule (2), for the words "shall be notified in the Official Gazette", the words "shall be published" shall be substituted.

60. In rule 117 of the principal rules,-
   (a) in sub-rule (1), for the word and figures "Form 24", the word and figures "Form 23" shall be substituted;
   (b) in sub-rule (3), for the words "shall be notified by the Controller in the Official Gazette", the words "shall be published" shall be substituted.

61. In rule 118 of the principal rules, in sub-rule (2), for the words "shall be notified in the Official Gazette", the words "shall be published" shall be substituted.

62. In rule 120 of the principal rules, the words "in the Official Gazette and in such other manner as the Controller may deem fit" shall be omitted.

63. For rule 121 of the principal rules, the following rules shall be substituted, namely:

"121. Period within which copies of specification etc are to be filed.- The period within which copies of specification or corresponding documents to be filed by the applicant under sub-section (1) of section 138 shall be three months from the date of communication by the Controller.

121A. Address of Communications.- All communications in relation to any proceeding under the Act or these rules shall be addressed to the Controller at the appropriate office.".

64. In rule 123 of the principal rules, the words "in the Official Gazette'" shall be omitted.

65. In rule 124 of the principal rules,-
   (a) in sub-rule (1), the words "in the Official Gazette" shall be omitted;
   (b) in sub-rule (4), for the words "to the hearing of the Opposition to the grant of patents", the words "in the hearing of the opposition proceeding" shall be substituted.

66. For rule 129 of the principal rules, the following rule shall be substituted, namely:

"129. Exercise of discretionary power by the Controller,- Before exercising any discretionary power under the Act or these rules which is likely to affect an applicant for a patent or a party to a proceeding adversely, the Controller shall give such applicant or party, a hearing, after giving him or them, ten days notice of such hearing ordinarily.

67. In rule 130 of the principal rules, in sub-rule (1) and (2), for the word and figures "Form 25", the word and figures "Form 24" at both the places shall be substituted.

68. In rule 131 of the principal rules,-
   (a) in sub-rule (1), for the word and figures "Form 29" the word and figures "Form 27" shall be substituted;
   (b) in sub-rule (3), the words "in the official Gazette and in such other manner as he may deem fit" shall be omitted.

69. In rule 134 of the principal rules, in sub-rule (1), for clauses (f), (g) and (k), the following clauses shall respectively be substituted, namely:
   "(f) as to when an application for patent has been refused;
   (g) as to when a patent has been granted;
   (k) as to when any application is made or action taken involving an entry in the register, publication in the Official Gazette or otherwise, if the nature of the application or action is specified in the request.".

70. For rule 138 of the principal rules, the following rule shall be substituted, namely:

"138 Power to extend time prescribed.- (1) Save as otherwise provided in the rules 24, 55 and 80(1A), the time prescribed by these rules for doing of any act or the taking of any proceeding thereunder may be extended by the Controller for a period of one month, if he thinks it fit to do so and upon such terms as he may direct.

(2) Any request of extension of time made under these rules shall be made before the expiry of prescribed period.".

71. For the First Schedule and the Second Schedule to the principal rules, the following Schedules shall be substituted, namely:

"THE FIRST SCHEDULE
(See rule 7)
FEES

Number of entry	On what payable	Number of the relevant Form	Amount of fees (in rupees)	
			For natural person(s)	For other than natural person(s) either alone or jointly with natural person(s)
1	2	3	4	5
			Rupees	Rupees
1. (i) (ii)	On application for a patent under sections 7, 54 or 135 and rule 20 (1) accompanied by provisional/ complete specification- for each sheet of specification in addition to 30; for each claim in addition to 10.	1	1000 Multiple of 1000 in case of every multiple priority. (i) 100 (ii) 200	4,000 Multiple of 4,000 in case of every multiple priority (i) 400 (ii) 800
2. (i) (ii)	On filing complete specification after provisional upto 30 pages having upto 10 claims.- for each sheet in addition to 30; for each claim in addition to 10.	2	No fee (i) 100 (ii) 200	No fee (i) 400 (ii) 800
3.	On filing a statement and undertaking under section 8.	3	No fee	No fee
4. (i)	On request for extension of time under sections 53(2) and 142(4), rules 13(6), 80(1A) and 130.	4	300 per month	1200 per month
4. (ii)	On request for extension of time under section 27(1) and rule 24B(4)(ii).	4	(a) 1000 for first month (b) 2000 for second month (c) 3000 for third month	(a) 4000 for first month (b) 8000 for second month (c) 12000 for third month
5.	On filing declaration as to inventorship under rule 13(6).	5	No fee	No fee
6.	On application for postdating.	-	500	2,000
7.	On application for deletion of reference under section 19(2).	-	500	2,000
8. (i) (ii)	On claim under section 20(1); On request for direction under section 20(4) or 20(5).	6 6	500 500	2,000 2,000
9.	On notice of opposition to grant of patent under section 25(3).	7	1,500	6,000
10.	On giving notice that hearing before Controller will be attended under rule 62(2).	-	1,500	6,000
11.	On application under sections 28(2), 28(3) or 28(7)	8	500	2,000
12.	Request for publication under section 11A(2) and rule 23B.	9	2,500	10,000
13.	On application under section 44 for amendment of patent.	10	1,500	6,000

1	2	3	4	5
14.	On application for directions under sections 51(1) or 51(2).	11	1,500	6,000
15.	On request for grant of a patent under section 26(1) and 52(2)	12	1,500	6,000
16.	On request for converting a patent of addition to an independent patent under section 55(1).	-	1,500	6,000
17.	For renewal of a patent under section 53:			
(i)	before the expiration of the 2nd year from the date of patent in respect of 3rd year;	-	500	2,000
(ii)	before the expiration of the 3rd year in respect of the 4th year;	-	500	2,000
(iii)	before the expiration of the 4th year in respect of the 5th year;	-	500	2,000
(iv)	before the expiration of the 5th year in respect of the 6th year;	-	500	2,000
(v)	before the expiration of the 6th year in respect of the 7th year;	-	1,500	6,000
(vi)	before the expiration of the 7th year in respect of the 8th year;	-	1,500	6,000
(vii)	before the expiration of the 8th year in respect of the 9th year;	-	1,500	6,000
(viii)	before the expiration of the 9th year in respect of the 10th year;	-	1,500	6,000
(ix)	before the expiration of the 10th year in respect of the 11th year;	-	3,000	12,000
(x)	before the expiration of the 11th year in respect of the 12th year;	-	3,000	12,000
(xi)	before the expiration of the 12th year in respect of the 13th year;	-	3,000	12,000
(xii)	before the expiration of the 13th year in respect of the 14th year;	-	3,000	12,000
(xiii)	before the expiration of the 14th year in respect of the 15th year;	-	3,000	12,000
(xiv)	before the expiration of the 15th year in respect of the 16th year;	-	5,000	20,000
(xv)	before the expiration of the 16th year in respect of the 17th year;	-	5,000	20,000
(xvi)	before the expiration of the 17th year in respect of the 18th year;	-	5,000	20,000
(xvii)	before the expiration of the 18th year in respect of the 19th year;	-	5,000	20,000
(xviii)	before the expiration of the 19th year in respect of the 20th year;	-	5,000	20,000
18.	On application for amendment of application for patent / complete specification/ other related documents under section 57-	13		
	(i) before grant of patent;		500	2,000
	(ii) after grant of patent;		1,000	4,000

1	2	3	4	5
	(iii) where amendment is for changing name / address/ nationality/ address for service.		200	800
19.	On notice of opposition to an application under sections 57(4), 61(1) and 87(2) or to surrender a patent under section 63(3) or to a request under section 78(5).	14	1,500	6,000
20.	On application for restoration of a patent under section 60.	15	1,500	6,000
21.	Additional fee for restoration.	-	3,000	12,000
22.	On notice of offer to surrender a patent under section 63.	-	1,000	4,000
23.	Application for withdrawing the application under section 11B (4) and rule 26(1).	-	1,000	4,000
24.	On application for the entry in the register of patent of the name of a person entitled to a patent or as a share or as a mortgage or as licensee or as otherwise or for the entry in the register of patents of notification of a document under sections 69(1) or 69(2) and rule 90(1), or 90(2).	16	1,000 (In respect of each patent)	4,000 (In respect of each patent)
25.	On application for alteration of an entry in the register of patents or register of patent agent under rule 94(1) or rule 118(1).	-	200	800
26.	On request for entry of an additional address for service in the Register of Patents under rule 94(3).	-	500	2,000
27.	On application for compulsory license under sections 84(1), 91(1), 92(1) and 92A.	17	1,500	6,000
28.	On request for examination of application for patent- (a) under section 11B and rule 24(1); (b) under rule 20(4) (ii).	18	 2,500 3,500	 10,000 14,000
29.	On application for revocation of a patent under section 85(1).	19	1,500	6,000
30.	On application for revision of terms and conditions of licence under section 88(4).	20	1,500	6,000
31.	On request for termination of compulsory licence under section 94.	21	1,500	6,000
32.	On application for registration as a patent agent under rule 109(1) or 112.	22	2,000	-
33.	On request for appearing in the qualifying examination under rule 109(3).	-	1,000	-
34.	For continuance of the name of a person in the register of patent agent-	-	-	-

1	2	3	4	5
(i)	For the 1st year to be paid along with registration;	-	500	-
(ii)	For every year excluding the 1st year to be paid on the 1st April in each year.	-	500	-
35.	On application for duplicate certificate of patent agent under rule 111A.	-	1,000	-
36.	On application for restoration of the name of a person in the register of patent agents under rule 117(1).	23	1,000 (Plus continuation fee under entry number 36)	-
37.	On a request for correction of clerical error under section 78(2).	-	500	2,000
38.	On application for review or setting aside the decisions/ order of the controller under sections 77(1)(f) or 77(1)(g).	24	1,000	4,000
39.	On application for permission for applying patent outside India under section 39 and rule 71(1).	25	1,000	4,000
40.	On application for duplicate Patent under section 154, and rule 132.	-	1,000	4,000
41.	On request for certified copies under section 72 or for certificate under section 147, and rule 133.	-	1,000	4,000
42.	For certifying office copies, printed each.	-	500	2,000
43.	On request for inspection of register under section 72, inspection under rule 27 or rule 74A.	-	200	800
44.	On request for information under sections 127, 132 and 153; and rule 135.	-	300	1,200
45.	On form of authorization of patent agent.	26	No fee	No fee
46.	On petition not otherwise provided for.	-	1,000	4,000
47.	For supplying of photocopies of the documents per page.	-	4	4
48.	Transmittal fee for. International application.	-	2,000	8,000
49.	For preparation of certified copy of priority document and for transmission of the same to the International Bureau of World Intellectual Property Organization.	-	1,000	4,000
50.	On statement regarding working of a patented invention on a commercial scale in India under section 146(2) and rule 131(1).	27	No fee	No fee

Note: All the Forms/ Applications/ Requests/ Notice/ Petitions shall be filed in duplicate unless otherwise specified in the rules.

THE SECOND SCHEDULE
[See rule 8]
FORMS
LIST OF FORMS

Form No.	Section and rule	Title
1	2	3
1.	Sections 7, 54, and 135 and rule 20(1).	Application for grant of a patent.
2.	Section 10; rule 13.	Provisional/ Complete Specification
3.	Section 8 and rule 12.	Statement and undertaking.
4.	Sections 53(2) and 142(4), rule, 13(6), 24B(4)(ii), 80(1A) and 130.	Request for extension for time.
5.	Section 10(6) and rule 13(6)	Declaration as to inventorship
6.	Sections 20(1), 20(4) 20(5) and rules 34(1), 35(1) or 36(1).	Claim or request regarding any change in applicant for patent.
7.	Section 25(3) and rule 55A.	Notice of opposition on grant of a patent.
8.	Sections 28(2), 28(3) or 28(7) and rules 66, 67, 68.	Request or claim regarding mention of investor as such in a patent.
9.	Section 11A(2) and rule 24A.	Request for publication.
10.	Section 44 and rule 75.	Application for amendment of patent.
11.	Sections 51(1), 51(2) and rules 76, 77.	Application for direction of the controller.
12.	Sections 26(1) & 52(2) and rules 63A and 79.	Request for grant of patent.
13.	Section 57 and rule 81(1).	Application for amendment of the application for patent/ complete specification.
14.	Sections 57(4), 61(1), 63(3), 78(5) and 87(2) and rules 81(3)(b), 85(1), 87(2), 98(1), 101(3) or 124.	Notice of opposition to amendment/ restoration/ surrender of patent/ grant of compulsory license or revision of terms tehereof or to a correction of clerical errors.
15.	Section 60 and rule 84.	Application for restoration of patents.
16.	Sections 69(1) or 69(2) and rules 90(1) and 90(2)	Application for registration of title/ interest in a patent or share in it or registration of any document purporting to affect proprietorship of the patent.
17.	Sections 84(1), 91, 92 or 92A and rule 96.	Application for compulsory license.
18.	Section 11B and Rule 20(4)(ii) and 24B(1)(i).	Request for examination of application for patent.
19.	Section 85(1) and rule 96.	Application for revocation of a patent for non-working.
20.	Section 88(4) and rule 100.	Application for revision of terms and conditions of license.
21.	Section 94, rule 102(1).	Request for termination of compulsory licence.

1	2	3
22.	Rules 109(1) and 112.	Application for registration of Patent Agent.
23.	Section 130(2) and rule 117(1).	Application for the restoration of the name in the register of Patent Agents.
24.	Sections 77(1)(f), 77(1)(g) and rules 30(1) and 130(2)	Application for review/ setting aside controller's decision/ order.
25.	Section 39 and rule 71(1).	Request for permission for making patent application outside India.
26.	Sections 127, 132 and rule 135.	Form of authorization of a Patent Agent/ or any person in a matter or proceeding under the Act.
27.	Section 146(2) and rule 131(1).	Statement regarding the working of the Patented invention on commercial scale in India.

FORM-1 **THE PATENTS ACT 1970** **(39 OF 1970)** **&** **The Patents Rules, 2003** **APPLICATION FOR GRANT OF PATENT** **(See section 7, 54 & 135 and rule 20(1))**	**(FOR OFFICE USE ONLY)** Application No: Filing Date: Amount of Fee Paid: CBR No: Signature:

1. APPLICANT(S)		
Name	Nationality	Address
2. INVENTOR(S)		
Name	Nationality	Address

3. TITLE OF THE INVENTION	
4. ADDRESS FOR CORRESPONDENCE OF APPLICANT/ AUTHORIZED PATENT AGENT IN INDIA	Telephone No. Fax No. Mobile No. E-mail:

5. PRIORITY PARTICULARS OF THE APPLICATION(S) FILED IN CONVENTION COUNTRY				
Country	Application Number	Filing Date	Name of the Applicant	Title of the Invention

6. PARTICULARS FOR FILING PATENT COOPERATION TREATY (PCT) NATIONAL PHASE APPLICATION	
International application number.	International filing date as allotted by the receiving office.

7. PARTICULARS FOR FILING DIVISIONAL APPLICATION	
Original (first) application number.	Date of filing of Original (first) application

8. PARTICULARS FOR FILING PATENT OF ADDITION	
Main application/ patent Number	Date of filing of main application

9. DECLARATIONS:

(i) Declaration by the inventor(s)

I/We, the above named inventor(s) is/ are the true & first inventor(s) for this invention and declare that the applicant(s) herein is/ are my/ our assignee or legal representative.

(a) Date___________

(b) Signature(s)

(c) Name(s)

(ii) Declaration by the applicant(s) in the convention country

I/We, the applicant(s) in the convention country declare that the applicant(s) herein is/ are my/ our assignee or legal representative.

(a) Date__________

(b) Signature(s)

(c) Name(s) of the signatory

(iii) Declaration by the applicant(s):

I/We, the applicant(s) hereby declare(s) that:

- ❑ I am/ We are in possession of the above-mentioned invention
- ❑ The provisional/ complete specification relating to the invention is filed with this application.
- ❑ The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/ us before the grant of patent to me/ us.
- ❑ There is no lawful ground of objection to the grant of the Patent to me/us.
- ❑ I am/ We are the assignee or legal representative of true & first investors.
- ❑ The application or each of the applications, particulars of which are given in Para-5 was the first application in convention country/ countries in respect of my/ our invention.
- ❑ I/We claim the priority from the above mentioned application(s) filed in convention country/ countries and state that no application for protection in respect of the invention had been made in a convention country before that date by me/ us or by any person from which I/We derive the title.
- ❑ My/ our application in India is based on international application under Patent Cooperation Treaty (PCT) as mentioned in Para-6.
- ❑ The application is divided out of my/ our application particulars of which are given in Para-7 and pray that this application may be treated as deemed to have been filed on___________ under sec. 16 of the Act.
- ❑ The said invention is an improvement in or modification of the invention particulars of which are given in Para-8.

10. Following are the attachments with the application:

a) Provisional specification/ Complete specification

b) Complete specification (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies), No. of pages_____ No. of claims_________

c) Drawings (in conformation with the international application)/as amended before the International Preliminary Examination Authority (IPEA), as applicable (2 copies), No. of sheets____

d) Priority documents

e) Translation of priority document/ Specification/ International Search Report

f) Statement and undertaking on Form 3

g) Power of Authority
h) Declaration of inventorship on Form 5
i) Sequence listing in electronic form
j) ....

Fee Rs...........................in Cash/ Cheque/ Bank Draft bearing no..............................
Date..........................on..............................Bank.

I/We hereby declare that to the best of my/ our knowledge, information and belief the fact and matters stated herein are correct and I/We request that a patent may be granted to me/ us for the said invention.

Dated this.............................day of.......................20.........................

Signature:
Name:

To, The Controller of Patent
The Patent Office, at.................

Note: *Repeat boxes in case of more than one entry.
* To be signed by the applicant(s) or by authorized registered patent agent otherwise where mentioned.
* Tick (✔)/ cross (x) whichever is applicable/ not applicable in declaration in para-9.
* Name of the inventor and applicant should be given in full, family name in the beginning.
* Complete address of the inventor and applicant should be given stating the postal index no./ code, state and country.
* Strike out the column which is/ are not applicable.
* For fee: See First Schedule.

FORM-2
THE PATENT ACT 1970
(39 of 1970)
&
The Patents Rules, 2003
PROVISIONAL/ COMPLETE SPECIFICATION
(See section 10 and rule 13)

1. TITLE OF THE INVENTION

2. APPLICANT (S)
(a) NAME:
(b) NATIONALITY:
(c) ADDRESS:

3. PREAMBLE TO THE DESCRIPTION

PROVISIONAL	COMPLETE
The following specification describes the invention.	The following specification particularly describes the invention and the manner in which it is to be performed.

4. DESCRIPTION (Description shall start from next page.)

5. CLAIMS (not applicable for provisional specification. Claims should start with the preamble- "I/We claim" on separate page)

6. DATE AND SIGNATURE (to be given at the end of last page of specification)

7. ABSTRACT OF THE INVENTION (to be given along with complete specification on separate page)

Note:
*Repeat boxes in case of more than one entry.
* To be signed by the applicant(s) or by authorized registered patent agent.
* Name of the applicant should be given in full, family name in the beginning.
* Complete address of the applicant should be given stating the postal index no./ code, state and country.
* Strike out the column which is/ are not applicable.

FORM-3
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
STATEMENT AND UNDERTAKING UNDER SECTION 8
(See section 8, rule 12)

1. Namely of the applicant(s). I/We.[1]....._______________________________

____

____

hereby declare:

2. Name, address and nationality of the joint applicant: (i) that I/We have not made any application for the same/ substantially the same invention outside India.

Or

(ii) that I/We who have made this application No.______________Dated___________alone/ jointly with[2]..., made for the same/ substantially same invention, application(s) for patent in the other countries, the particulars of which are given below:

Name of the country.	Date of application	Application No.	Status of the application	Date of publication	Date of grant

3. Name and address of the assignee (iii) that the rights in the application(s) has/ have been assigned to......[3]_____________________________

____

that I/We undertake that upto the date of grant of the patent, by the Controller, I/We would keep him informed in writing the details regarding corresponding applications for patents filed outside India within three months from the date of filing of such application.

Dated this................day of...20

4. To be signed by the application or his authorized registered patent agent. Signature[4]..
5. Name of the natural person who has signed. ( )[5]

To
The Controller of Patents,
The Patent Office, At

Note: Strike out whichever is not applicable.

FORM-4
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
REQUEST FOR EXTENSION OF TIME
[See section 53(2) and 142(4) rules 13(6), 24B(4)(ii), 80(1A) and 130]

1. Name of the applicant(s). I/We.[1]....._______________________________

____

____

hereby request for extension of time for_________ month(s) under Section/ Rule__________ in connection with my/ our application/ Patent No.____________

The reasons for making the request are as follows:

Dated this..........................day of...................................20

2. To be signed by the applicant or his authorized registered patent agent.

Signature..2..

(--)[3]

3. Name of the natural person who has signed

To
The Controller of Patents,
The Patent Office,
At...
....

Note: For fee: See First Schedule.

FORM-5
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
DECLARATION AS TO INVENTORSHIP
[See Section 10(6) and rule 13(6)]

1. NAME OF APPLICANT (S)

hereby declare that the true and first inventor(s) of the invention disclosed in the complete specification filed in pursuance of my/ our application numbered_______________ dated_______________ is/ are_______________________

2. INVENTOR(S)
   (a) NAME
   (b) NATIONALITY
   (c) ADDRESS

Dated this.........................day of...................20...................
Signature:
Name of the signatory:

3. DECLARATION TO BE GIVEN WHEN THE APPLICATION IN INDIA IS FILED BY THE APPLICANT(S) IN THE CONVENTION COUNTRY:
   We the applicant(s) in the convention country hereby declare that out right to apply for a patent in India is by way of assignment from the true and first inventor(s).

Dated this.........................day of...................20...................
Signature:
Name of the signatory:

4. STATEMENT (to be signed by the additional inventor(s) not mentioned in the application form)
   I/We assent to the invention referred to in the above declaration, being included in the complete specification filed in pursuance of the stated application.

Dated this.........................day of...................20...................
Signature:
Signature of the additional inventor(s):-
Name:-

To, The Controller of Patent
The Patent Office, at.............

Note:

*Repeat boxes in case of more than one entry.
* To be signed by the applicant(s) or by authorized registered patent agent otherwise where mentioned.
* Name of the inventor and applicant should be given in full, family name in the beginning.
* Complete address of the inventor should be given stating the postal index no./ code, state and country.
* Strike out the column which is/ are not applicable.

FORM-6
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
CLAIM OR REQUEST REGARDING ANY CHANGE IN APPLICANT FOR PATENT
[See Section 20(1), 20(4) AND 20(5); rules 34(1), 35(1) and 36(1)]

I/We, [1].___________________________________
(a) [2] ___________________________________
(b) [3] ___________________________________
(c) [4] ___________________________________

hereby request that the application for patent No............................dated...........................
made by5.________________________________
____
may proceed in my/ our name and further request that direction of the Controller, if necessary be made in that effect

Reasons for making the above request are as follows:
____
____

I furnish the following document(s) in support of my above request:[6]
(a) [7]________________________
(b) [7]________________________
(c) [7]________________________

My/our address for service in India is:.[8.]

1. Repeat the columns (a) to (c) if there are more than one applicant.
2. Insert the name in full. The family or principal name in the beginning if the applicant is a natural person.
3. Insert the complete address including postal index number/ code and state and/ or country.
4. Insert the nationality.
5. State the name of the applicant(s) for patent.
6. Original and certified copies of the documents shall accompany the claim or request. Consent by the legal representative of the deceased joint applicant shall be filed whenever required.
7. Insert the details of the documents.
8. Complete address including postal index number/ code and state along with Telephone and fax number(s).
9. To be signed by the applicant(s) or authorized registered patent agent.
10. Name of the natural person who has signed.

Dated this.........................day of...................200
Signature:[9]
(---)[10..]

To
The Controller of Patents,
The Patent Office,
At......................................

N.B.: This form is not applicable for mere change of name.
Note: (a) Strike out whichever is not applicable.
(b) For fee: See First Schedule.

FORM-7
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
NOTICE OF OPPOSITION
[See Section 25(3), and 55A]

1. State names, address and nationality. — I/We, [1].____________________________________
____
____
____

2. State the grounds taken one after another. — hereby give notice of opposition to patent No...........................) granted on application No.................dated............................ published on dated..........................made by______________________ on the grounds[2].

3. Complete address including postal index number/ code and state along with Telephone and fax number. — ____
____

4. To be signed by the opponent or by his authorized registered patent agent. — My/ Our address for services in India is...[3.]
....
....

5. Name of the natural person who has signed. — Signature[..4]....
(---)[5].....

To
The Controller of Patents,
The Patent Office,
At..

For fee: See First Schedule.

FORM-8
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
REQUEST OR CLAIM REGARDING MENTION OF INVENTOR AS SUCH IN A PATENT
[See Section 28(2), 28(3) and 28(7); rules 66, 67 and 68]

1. State names, address and nationality of the person making this application. — I/We, [1].____________________________________
____
____
hereby state/ claim that the following person(s) be mentioned as inventor(s) in the patent application No................................dated.....................made by____ or hereby declare that.[2..]

2. Insert the name of the person mentioned as inventor. — ....
....
ought not to have mentioned as inventor in the application for Patent No..................dated................made by...and I/ We hereby apply for a certificate to that effect.

3. Complete address including postal index number/ code and state along with Telephone and fax number(s).

A Statement setting out the circumstances under which this application is made is attached together with the copy/ copies thereof as required under the rules.

4.	To be signed by the applicant or his authorized registered patent agent.	My/ Our address for services in India is...[3.] .... Dated this.......................day of 20
5.	Name of the natural person who has signed.	Signature[..4].... (---)[5].....

To
The Controller of Patents,
The Patent Office,
At...

Note: For fee: See First Schedule.

FORM-9

THE PATENTS, ACT, 1970

(39 of 1970)

&

The Patents Rules, 2003

REQUEST FOR PUBLICATION

[See Section 11A(2); rule 24A]

1.	Name, address and nationality of the applicant(s).	I/We, [1].____________________________________ ____ ____
2.	To be signed by the applicant or his authorized registered patent agent.	hereby request for early publication of my/our application for Patent No.............dated.............under section 11A(2) of the Act. Dated this................day of.............................20
3.	Name of the natural person who has signed.	Signature[..2]... (--)[3].... To The Controller of Patents, The Patent Office, At...

Note: For fee: See First Schedule

FORM-10

THE PATENTS, ACT, 1970

(39 of 1970)

&

The Patents Rules, 2003

APPLICATION FOR AMENDMENT OF PATENT

[See Section 44; rule 75]

1.	Repeat the columns (a) to (c) if there are more than one applicant.	I/We, [1].____________________________________ (a) [2.] ______________________________________ (b) [3]. ______________________________________ (c) [4]. ______________________________________
2.	Insert the name in full. Family or principal name in the beginning if the applicant is a natural person.	(a) [2.] ______________________________________ (b) [3]. ______________________________________ (c) [4]. ______________________________________
3.	Insert the complete address including postal index number/ code and state and/ or country.	(a) [2.] ______________________________________ (b) [3]. ______________________________________ (c) [4]. ______________________________________
4.	Insert the nationality.	____ hereby request that Patent No.---------------------------- dated______________granted_______________to __________________________________

5.	Complete address including postal index number/ code and state along with Telephone and fax number(s).	may be amended by substituting my/ our name for the name of the grantee and in support to my/ our request, I/We furnish the following documents: .... My/our address for service in India is.[5]... .... Dated this ....day of 20
6.	To be signed by the applicant(s) or his authorized registered patent agent.	Signature.[6]............
7.	Name of the natural person who has signed.	(---).[7].. To The Controller of Patents, The Patent Office, At..

Note: For fee: See First Schedule

FORM-11
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
APPLICATION FOR DIRECTION OF THE CONTROLLER
[See Section 51(1) AND 51(2); rule 76 and 77]

1.	State the name in full, address and nationality.	I/We, [1].____________________________________ ____________________________________ ____________________________________ hereby apply for the following direction in respect of patent No.------------------------------dated......... grant to---
2.	Complete address including postal index number/ code and state along with Telephone and fax number(s).	The reasons for making this application are as follows: ....
3.	To be signed by the applicant(s) or his authorized registered patent agent.	My/ Our address for service in India is.[2]................. .... Dated this....................day of..........................20 Signature..[3]...
4.	Name of the natural person who has signed.	(---)..[4].. To The Controller of Patents, The Patent Office, At..

Note: For fee: See First Schedule

FORM-12
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
REQUEST FOR GRANT OF PATENT UNDER SECTION 26(1) & 52(2)
[See Section 26(1) & 52(2); rule 63a AND 79]

1.	Repeat the columns (a) to (c) if there are more than one applicant.	I/We, [1]--- --- ---

(a) [2]--

(b) [3]--

(c) [4]--

hereby declare:

(i) that I/We made opposition under section 25(3) before the Controller or a petition under Section 64 of the Act before the Appellate Board or High Court of [5]..
and the details of the patent and the opposition for the petition are given below:

Patent No...dated.................
Grantee/ Patentee.................................Opposition.
Notice dated.........................or Petition No...dated..........................

(ii) that I/We have claimed to be the true and first inventor(s)/ assignee(s)/ legal representative(s) of [6].
....
....
the true and first inventor of the invention for which the said patent was granted.

(iii) that by an order in the said opposition or petition the patent was revoked/ the complete specification of the patent was directed to be amended by exclusion of...claims thereof.

(iv) that the Controller or Appellate Board or Court ordered to grant to me a patent in lieu of the said patent/ part of the invention excluded by the amendment.

(v) that I/We submit a statement and certified copy of the order of the Controller or Appellate Board or Court in support of may application and request that a patent be granted to me in accordance with the order of the Appellate Board or Court.

My/ Our address for service in India is. [7].
....
....
Dated this.......................day of.......................200
Signature. [8]......
(--).[9]..
To
The Controller of Patents,
The Patent Office,
At...

2. Insert the name in full. Family or principal name in the beginning, if the applicant is a natural person.
3. Insert the complete address including postal code and state and/ or country.
4. Nationality of the person.
5. Name of the High Court.
6. Name, address and nationality or the true and first inventor.
7. Complete address including postal index number code and state along with Telephone and fax number(s).
8. To be signed by the applicant(s) or his authorized registered patent agent.
9. Name of the natural person who has signed.

Note: (a) Strike out whichever is not applicable.
(b) For fee: See First Schedule.

FORM-13
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
APPLICATION FOR AMENDMENT OF THE APPLICATION FOR PATENT/ COMPLETE SPECIFICATION
[See Section 57; rule 81(1)]

I/We, [1]--

----

1. Name of the applicant(s).

2. To be signed by the applicant(s) or patentee(s) or by his authorized registered patent agent.

3. Name of the natural person who has signed.

request leave to amend the application/ complete specification with respect to application for patent No. ....dated.................................
as highlighted in the copy hereto annexed.
My/ Our reasons for making this request are as follows:
....
....
....
I/We declare that no action for infringement or for the revocation of the patent in question is pending before Appellate Board or a Court.
I/We declare that the facts and matters stated herein are true to the best of my/ our knowledge information and belief.
Dated this.....................day of.....................200

Signature. [2]......
(---).[9]..
To
The Controller of Patents,
The Patent Office,
At..

Note: For fee: See First Schedule.

FORM-14
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003

NOTICE OF OPPOSITION TO AMENDMENT/ RESTORATION/ SURRENDER OF PATENT/ GRANT OF COMPULSORY LICENCE OR REVISION OF TERMS THEREOF OR TO CORRECTION OF CLERICAL ERRORS

[See Section 57(4), 61(1), 63(3), 78(5) and 87(2); rules 81(3)(b), 85(1), 87(2), 98(1), 101(3), and 124]

1. State the name, address and nationality.

2. Complete address including postal index number/ code and state along with Telephone and fax number(s).

I/We, [1]---
----
hereby give notice of opposition:
to the amendment of the application/ specification with respect to application for Patent No................ dated...........

OR

to the application for restoration of Patent No............dated.......................

OR

to the offer to surrender the Patent No.......................dated.............

OR

for the grant of compulsory licence, or revocation of Patent No..........................dated.......................

OR

3.	To be signed by the opponent or his authorized registered patent agent.	for the revision of the terms and conditions of licence in respect of Patent No. ....dated............... OR for correction of a clerical error in Patent No..................dated............../ Specification No........... dated...........in respect of Patent No..................dated........ or Patent application No...................dated....................
4.	Name of the natural person who has signed.	The grounds in which the said opposition is made are as follows: .... My/ Our address for service in India is:[2]. .... Dated this.................day of.......................20 Signature. [3]..... (---).[4].. To The Controller of Patents, The Patent Office, At...

Note: (a) Strike out whichever is not applicable.
(b) For fee: See First Schedule.

FORM-15
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
APPLICATION FOR THE RESTORATION OF PATENT
[See section 60; rule 84]

1.	Inserted the name, address, nationality of the applicant(s)	I/We, [1]--- -- -- hereby apply for an order of the Controller for the restoration of Patent No........................dated................. granted to... The circumstances which led to the failure to pay the renewal fee to pay the renewal fee for the year................ on or before......................................are as follows: .... I/We declare that I/We have not assigned the patent to any other person(s) and that the facts and matters stated herein are true to the best of my/our knowledge information and belief. Dated this..................day of............................20
2.	To be signed by the applicant(s) or by his authorized registered patent agent.	Signature.[2]............. (---)[3]
3.	Name of the natural person who has signed.	To The Controller of Patents, The Patent Office, At...

Note: For fee: See First Schedule.

FORM-16
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003

APPLICATION FOR REGISTRATION OF TITLE/ INTREST IN A PATENT OR SHARE IN IT OR REGISTRATION OF ANY DOCUMENT PURPORTING TO AFFECT PROPRIETORSHIP OF THE PATENT

[See sections 69(1), 69(2); rules 90(1) and 90(2)]

1.	Insert the name, address and nationality of the applicant(s)	I/We, [1]-- --- hereby apply that my/our name(s) may be registered in the register of patent as a person entitled to the patent/a share in the patent/ an interest in the patent details of which are specified below:
2.	A description of the nature of the document, giving the date and the names, address and nationality of the parties thereto.	Patent No.......................dated.................Grantee........... Patentee...............................and in proof thereof we transmit the accompanying[2]... with a certified copy thereof. OR Transmit herewith an attested copy of[2]........... ....in
3.	Complete address including postal code and state along with telephone and fax number(s).	respect of Patent No(s)...................dated.............granted to.......................................of which the patentee is ....as well as the original document for verification and I/We hereby apply that a notification thereof may be entered in the register of patents.
4.	To be signed by the applicant or his authorized registered patent agent.	My/ Our address for service in India is[3]. ....
5.	Name of the natural person who has signed.	Dated this.................day of.......................20 Signature. [4]..... (---).[5].. To The Controller of Patents, The Patent Office, At..

Note: (a) For fee: See First Schedule.
(b) Strike out whichever is not applicable.

FORM-17
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003

APPLICATION FOR COMPULSORY LICENCE

[See sections 84(1), 91, 92(1) or 92A; rule 96]

1.	Name, address and nationality of the applicant(s).	I/We, [1]-- --- hereby apply for the grant of a compulsory licence under
2.	Certified copies of the documents are to be enclosed in duplicate.	Patent No....................dated.........................Granted to.................................... for which the patentee is........................on the following grounds, namely:

3. Complete address including postal code and state along with telephone and fax number(s).	.... I/We declare that the facts and matters stated herein are true to the best of my/ our knowledge, information and belief.
4. To be signed by the applicant(s) or by his authorized registered patent agent.	The details of documentary evidence in support of my/ our interest and the grounds stated above are given below[2]...................................... (a) .... (b) .... (c) .... My/ Our address for service in India is:[3].................. .... Dated this.......................day of 20
5. Name of the natural person who has signed.	Signature. [4]..... (---).[5].. To The Controller of Patents, The Patent Office, At...

Note: For fee: See First Schedule.

FORM18 **THE PATENTS ACT, 1970** **(39 OF 1970)** **&** **The Patents Rules, 2003** **REQUEST/ EXPRESS REQUEST FOR EXAMINATION OF APPLICATION FOR PATENT** **[See section 11B and rule 20(4)(ii), 24B(1)(i)]**	**(FOR OFFICE USE ONLY)** RQ. No. Filing Date: Amount of Fee Paid: CBR No: Signature:

1. APPLICANT(S)/ OTHER INTERESTED PERSON

(a) NAME:

(b) NATIONALITY:

(c) ADDRESS:

2. Statement in case of request for examination made by the applicant(s)

I/We hereby request that my/ our application for patent no________________ filed on_______________ for the invention titled ____shall be examined under sections 12 and 13 of the Act.

Or

I/We hereby make an express request that my/ our application for patent no. ______________filed on _______________________based on Patent Cooperation Treaty (PCT) application no. _____________ dated_______________ made in country _____________________shall be examined under sections 12 and 13 of the Act, immediately without waiting for the expiry of 31 months as specified in rule 20(4)(ii).

3. Statement in case of request for examination made by any other interested person

I/We the interested person request for the examination of the application no ___________ dated _____________ filed by the applicant ____________titled ______________________ under sections 12 and 13 of the Act.

As an evidence of my/ our interest in the application for patent following documents are submitted

(a) __________________________________

____

4. ADDRESS FOR SERVICE
Dated this _____________ day of ____________ 20 Signature Name of the signatory To, The Controller of Patent The Patent Office, at.............
NOTE: *To be signed by the applicant(s) or by his authorized registered patent agent * Strike out the column which is/ are not applicable. *For Fee: See First Schedule

FORM-19
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
APPLICATION FOR REVOCATION OF A PATENT
FOR NON WORKING
[See sections 85(1); rule 96]

1.	Name, address and nationality of the applicant(s).	I/We, [1]-- -- --
2.	State the nature of the applicant's interest, the facts on which he relies and the grounds on which the application is made.	hereby apply for revocation of Patent No...........dated..........granted to............................ for which the patentee/ applicant for patent is ....for the following reason, namely: [2].. ....
3.	Certified copies of all the documents are to be enclosed in duplicate.	The details of documentary evidence in support of my/our interest and the reasons stated above are given below:[3]... (a)........................... .... (b) .... (c) ....
4.	Complete address including postal index number/ code and state along with telephone and fax number(s).	I/We declare that the facts and matters stated herein are true to the best of my/ our knowledge, information and belief. My/Our address for service in India is.[4]
5.	To be signed by the application(s) or his authorized registered patent agent.	.... Dated this.......................day of.......................20 Signature. [5]................
6.	Name of the natural person who has signed.	(--).[6].. To The Controller of Patents, The Patent Office, At...

Note: (a) For fee: See First Schedule.

FORM-20
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
APPLICATION FOR REVISION OF TERMS AND CONDITIONS OF LICENCE
[See sections 88(4); rule 100]

1.	Name, address and nationality of the applicant(s).	I/We, [1]--- --- --- hereby declare:
2.	To be signed by the applicant(s) or by his authorized registered patent agent.	(i) that Patent No.............. dated.......... was granted to .... for which the patentee is .... (ii) that I/We am/ are holding licence under the patent, granted by the Controller by an order dated................
3.	Name of the natural person who has signed.	(iii) that the terms and conditions settled by the Controller have proved to be more onerous than originally expected and we are unable to work the invention. (iv) that the circumstances in which this application is made are set forth in the accompanying statement in duplicate. I/We request the Controller to revise the terms and conditions of the licence. Dated this......................day of.......................20 Signature. [2]................ (---).[3].. To The Controller of Patents, The Patent Office, At...

Note: (a) For fee: See First Schedule.
(b) Strike out whichever is not applicable.

FORM-21
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
REQUEST FOR TERMINATION OF COMPULSORY LICENCE
[See sections 94; RULE 102(1)]

1.	Name, address and nationality of the applicant(s).	I/We, [1]--- -- --
2.	Certified copies of the documents are to be enclosed in duplicate.	hereby apply for the termination of the compulsory licence granted to---by the order of the Controller dated --------------------------under patent No/ No---------------------------dated ----------------------granted to --------------------------------------for which the patentee------- -------------------------------- I/We declare that I am/We are the patentee for the above mentioned patent. I/We declare that I/We derive title/ interest in the patent. I/We make the above mentioned request for termination on the following grounds, namely:

3.	Complete address including postal code and state along with telephone and fax number(s).	-- -- I/We declare that the facts and matters stated herein are true to the best of my/our knowledge, information and belief. The details of documentary evidence in support of my/ our interest and the grounds stated above are given below:[2]
4.	To be signed by the applicant(s) or by his authorized registered patent agent.	(a) --- (b) --- (c) --- My/our address for service in India is:[3]
5.	Name of the natural person who has signed.	Dated this --------------------day of -------------------20 Signature.[4] (---).[5].. To The Controller of Patents, The Patent Office, At...

FORM-22
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
APPLICATION FOR REGISTRATION OF PATENT AGENT
[See sections 109(1) and 112]

1.	Certificate testifying to the character of the applicant should be from a person not related to him and being a Gazetted Officer or any other Person whom the Controller thinks fit.	I beg to apply for registration as a patent agent under the Patents Act, 1970 A certificate of character[1] From --- --- --- is enclosed herewith. I hereby declare that I am not subject to any of the dis-qualifications specified in rule 114 of the Patents Rules 2003 and that the information given below is true to the best of my knowledge and belief. Name:[2]-- ---
2.	Family or principal name in the beginning.	Address/ place of residence-------------------------------------- --- --- Principal place of business: -------------------------------------- --- --- Address of the branch office if any: --- ---
3.	Either original certificates and other documents or copies thereof duly attested by the Gazetted Officer or any other person whom the Controller thinks fit must be sent with the application.	Father's name: -- --- Nationality: --- Date and place of birth: --- --- Occupation: --- Particulars of qualification for registration as patent agent.[3] (a) -- (b) -- (c) --

4.	To be signed by the applicant.	Dated this ------------------------- day of----------------20-------- Signature[4] ------------------------- (---)[5] To The Controller of Patents The Patent Office at----------------------------

Note: (a) For fee: See First Schedule
(b) Attach two recent passport size photographs
(c) Provide specimen signature in separate sheet.

FORM-23
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
APPLICATION FOR THE RESTORATION OF THE NAME IN THE REGISTER OF PATENT AGENTS
[See sections 103(2); rule 117(1)]

		I, --- hereby apply for the restoration of my name in the register of patent agent which was removed on------------------------- under section 130 or Rule 116. My name was originally entered in the register on----------------------------------- under No.--- Dated this ----------------------day of ---------------------20-----
1.	To be signed by the applicant.	Signature[1]---------------------------------
2.	Name of the natural person who has signed.	(---)[2] To The Controller of Patents The Patent Office at-----------------------------

Note: (a) For fee: See First Schedule.

FORM-24
THE PATENTS, ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
APPLICATION FOR REVIEW/ SETTING ASIDE CONTROLLER'S DECISION/ ORDER
[See sections 77(1)(f) and 77(1)(g) and rules 130(1) and 130(2)]

1.	State the number of patent or patent application number and the relevant proceeding.	In the matter of[1] -- -- --
2.	Name, address and nationality of the applicant(s).	I/We[2]-- -- -- being the applicant(s)/ opponent/ party in the above matter hereby apply for the review/ setting aside of the Controller's decision/ order dated the ---in the above matter. The grounds for making the application are set forth in the accompanying statement submitted in duplicate.

Dated this.............................day of..............................20....................

3.	To be signed by the applicant(s) or his authorized registered patent agent.	Signature[3]-- (---)[4]
4.	Name of the natural person who has signed.	To The Controller of Patents The Patent Office at-----------------------------

Note: For fee: See First Schedule.

FORM-25

THE PATENTS, ACT, 1970

(39 of 1970)

&

The Patents Rules, 2003

No Fee REQUEST FOR PERMISSION FOR MAKING PATENT APPLICATION OUTSIDE INDIA

[See sections 39 and Rule 71(1)]

1.	State the title of the invention.	I am/ We are in possession of an invention for[1]--------------- -- -- I/We have made an application for the grant of a patent for the said invention, its number being No. ------------------- ------------ of------------------------------- Dated ------------------- OR
2.	Name, address of the person(s).	I/We hereby attach the brief description of the invention. I/We intend to make application(s) alone/ Jointly with[2]------ -- --
3.	Name and address of the assignee	for the same/ substantially same invention for patent in the following country/ countries/ convention countries, namely: -- ---I/We declare the rights in the application(s) has/ have been assigned to [3].--- --- I/We request that I/We may be granted permission to make application(s) for the said country/ countries. The reasons for making this application, are as follows:
4.	To be signed by the applicant(s) or his authorized patent agent.	Signature[4]--------------------------------------- To The Controller of Patents The Patent Office at-----------------------------

Note: (a) Strike out whichever is not applicable.

FORM-26

THE PATENTS, ACT, 1970

(39 of 1970)

&

The Patents Rules, 2003

FORM FOR AUTHORISATIONOF A PATENT AGENT/ OR ANY PERSON IN A MATTER OR PROCEEDING UNDER THE ACT

[See sections 127 and 132; and rule 135]

1.	Insert name, address and nationaliy.	I/We[1] --- -- --

2.	Insert the name, address and nationality of the person(s) to be authorized.	hereby authorize[2]--- -- --
3.	State the particular matter or proceeding for which the authorization is made.	to act on my/ our behalf in connection with[3] ------------------- -- and request that all notices, requisitions and communication relating thereto may be sent to such person at the above address unless otherwise specified.
4.	To be signed by the person(s) making this authorization.	I/We hereby revoke all previous authorixation, if any made, in respect of same matter or proceeding. I/We hereby assent to the action already taken by the said person in the above-matter. Dated this..............day of................../20...............
5.	Name of the natural person who has signed along with designation and official seal, if any.	Signature[4]--------------------------------------- (--)[5] To The Controller of Patents The Patent Office at-----------------------------

To be stamped under the Indian Stamp Act, 1899 (2 of 1899).

FORM-27

THE PATENTS, ACT, 1970

No Fee **(39 of 1970)**

&

The Patents Rules, 2003

STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON COMMERCIAL SCALE IN INDIA

[See sections 146(2) and rule 131(1)]

1.	Insert name, address and nationaliy.	In the matter of Patent No.---------------------of------------- I/We[1] -- -- ---
2.	State the year to which the statement relates	The patentee(s) or licensee(s) under Patent No......hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year[2]---
3.	Give whatever details are available.	[3] (i) The patented invention: { } Worked { } Not worked [Tick (✓) mark the relevant box] (a) if not worked: reasons for not working and steps being taken for working of the invention. (b) If worked: quantum and value (in Rupees), of the patented product: i) manufactured in India ii) imported from other countries. (give country wise details) (ii) the licenses and sub-licenses granted during the year; (iii) state whether public requirement has been met partly/ adequately/ to the fullest extent at reasonable price. The facts and matters stated above are true to the best of my/ our knowledge, information and belief. Dated this......................day of...................200..............

4. To be signed by person(s) giving the statement.

Signature[4]...................................
To
The Controller of Patents
The Patent Office
at......................

Note: (a) Strike out whichever is not applicable.".

2. For the Fourth Schedule to the principal rules, the following Schedule shall be substituted, namely:

"THE FOURTH SCHEDULE

[See proviso to rule 136(1)]

Number of entry	Matter in respect of which cost is to be awarded	Amount of fees (in Rupees)	
		For natural person(s)	For other than natural person(s) either alone or jointly with natural person(s)
1	2	3	4
1.	For notice of opposition: under sections 25, 57, 60, 63, 78, 87(2) or 88(4);	1,500	6,000
2.	For application for compulsory license: under sections 84(1), 91(1) or 92(1);	1,500	6,000
3.	For application for revision of terms and conditions of license; under section 88(4).	1,500	6,000
4.	For notice of intention to attend the hearing under rule 62(2).	1,500	6,000
5.	Stamp fee for power of attorney, where a patent agent or other person has been appointed or stamp fee in respect of relevant affidavits.	The amount actually paid	The amount actually paid
6.	For written statement under rule 57 or reply statement under rule 58 or for each affidavit, it relevant.	2,500	2,500
7.	For each document or publication produced in the proceedings, if relevant.	1,000	1,000
8.	For each unnecessary or irrelevant affidavit or citation.	1,000	1,000
9.	For every day or part day of hearing before the Controller.	2,500	2,500.".

[No. 14/3/2004-PP & C]

ANTHONY DESA, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide Notification number S.O.493(E) dated the 2nd May, 2003.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,
ರಿಚಾರ್ಡ್ ಲೋಬೋ
ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ
ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,
ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 117

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 116 ಕೇನಿಪ್ರ 2005, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 18ನೇ ಏಪ್ರಿಲ್, 2005

2004ನೇ ಸಾಲಿನ ಡಿಸೆಂಬರ್ 21ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ-II ಸೆಕ್ಷನ್ 3(i)ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ G.S.R.821(E) [F.No.P.15014/10/2002-PH (Food) ದಿನಾಂಕ: 21.12.2004 ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health)
NOTIFICATION
New Delhi, the 21st December, 2004

G.S.R.821(E): Whereas a draft of certain rules further to amend the Prevention of Food Adulteration Rules, 1955 was published, as required by sub-section (1) of section 23 of the Prevention of Food Adulteration Act, 1954 (37 of 1954) and published at pages 1 to 30 in the Gazette of India, Extraordinary Part II, section 3, sub-section (i), dated the 11th June, 2003 under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number GSR 477 (E), dated the 11th June, 2003 for inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of sixty days from the date on which the copies of the Official Gazette containing the said notification, were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the 16th June, 2003;

And whereas objections or suggestions received from the public within the specified period on the said draft rules have been considered by the Central Government.

Now, therefore, in exercise of the powers conferred by section 23 of the said Act, the Central Government, after consultation with the Central Committee for Food Standards, hereby makes the following rules further to amend the Prevention of Food Adulteration Rules, 1955, namely:

1. (1) These rules may be called the Prevention of Food Adulteration (.........Amendment) Rules, 2004.
   (2) They shall come into force after the expiry of a period of six months from the date of their publication in the Official Gazette.
2. In the Prevention of Food Adulteration Rules, 1955 (therein after referred to as the said rules), in Appendix B, after item A34 and entries relating thereto, the following shall be inserted, namely:

"A.35- Fish and Fish Products

A.35.01 Frozen Shrimps or Prawns means the product prepared from fresh srimps of sound quality belonging to Penaeidae, Pandalidae, Crangonidae, Palaeomonidae Solenoceridae, Aristeidae and Sergestidae families. The product shall not contain a mixture of genera but may contain mixture of species of same genus with similar sensory properties. The product may be peeled or unpeeled, raw or cooked. The product maybe glazed with water. The product shall conform to the following requirements:

Sl. No.	Characteristics	Requirements in Raw Product	Requirement in Cooked Product
(1)	Total Volatile Base (Nitrogen)	Not more than 30 mg/ 100 gm	Absent in 25gm

A 35.02 Frozen Lobsters means the product prepared from fresh lobsters of sound quality belonging to the genus Homarus of the family Nephropidae and from the families Palinuridae and Scyllaride. The Norway Lobster may be prepared from Nephros norvegicus. The product shall not be a mixture of different species. The product may be raw or cooked. The product may be glazed with water. The product shall conform to the following requirements:

Sl. No.	Characteristics	Requirements in Raw Product	Requirement in Cooked Product
(1)	Total Volatile Base (Nitrogen)	Not more than 30 mg/ 100 gm	Absent in 25gm

A 35.03 Frozen squid and parts of squid means the product prepared from fresh squid of sound quality belonging to squid species of Loliginidae, Ommastrephidae Onlychoteuthidae and Thysanotenthidae families. The product may be glazed with water. No food additive is allowed in this product. The product shall conform to the following requirements:

Sl. No.	Characteristics	Requirements in Raw Product
(1)	Total Volatile Base (Nitrogen)	Not more than 30 mg/ 100 gm

A 35.04 Frozen finfish means the product prepared from fresh fish of good quality. The product may be with or without head from which viscera or other organs have been completely or partially removed. The product may be glazed with water. The products shall conform to the following requirements:

Sl. No.	Characteristics	Requirements
(1)	Total Volatile Base (Nitrogen)	Not more than 30 mg/ 100 gm
(2)	Histamine	Not more than 20 mg/ 100 gm

A. 35.05 Frozen fish fillets or minced fish flesh or mixtures thereof are products obtained from fresh wholesome fish of any species or mixture of species with similar-sensory properties. Fillets may be pieces of irregular size and shape with or without skin. Minced fish flesh consists of particles of skeletal muscle." and is free from bones, viscera and skin. The product may be glazed with water. The products shall conform to the following requirement:

Sl. No.	Characteristics	Requirements
(1)	Total Volatile Base (Nitrogen)	Not more than 30 mg/ 100 gm
(2)	Histamine	Not more than 20 mg/ 100 gm

Note I: Products under item A.35.01, 35.02, 35.03, 35.04 and 35.05 shall be frozen in an appropriate equipment quickly to minus (-) 18^{0}C or colder in such a way that the range of temperature of maximum crystallization is passed quickly. The quick freezing process shall not be regarded as complete unless the product temperature has reached minus (-) 18^{0}C or colder at the thermal center after thermal stabilization. The product shall be kept deep frozen so as to maintain the quality during transportation, storage and sale. The entire operation including processing and packaging shall ensure minimum dehydration and oxidation. The product may contain food additives permitted in Appendix C except listed product under item A35.03. The product shall conform to the microbiological requirement given in Appendix D. The products shall be free from any foreign matter and objectionable odour/ flavour.

A 35.06 Dried shark fins means the product prepared from dorsal and pectoral fins, lower lobe of caudal fin and Pelvic from fresh shark of edible quality. The product shall be free from adhering flesh and may be with or without skin. The product shall be dried in a suitable manner and shall be free from any food additive. The product shall be free from foreign matter, objectionable odour or flavour and rancidity. No food additive is allowed in this product. The products shall conform to the following requirements:

Sl. No.	Characteristics	Requirements
(1)	Moisture	Not more than 10.0 percent
(2)	Ash insoluble in HCL on dry basis	Not more than 1.0 percent
(3)	Yeast and Mould Count	Absent in 25gm

A. 35.07 Salted fish/ dried salted fish means the product prepared from fresh wholesome fish. The fish shall be bled, gutted, beheaded, split or filleted and washed. The fish shall be fully saturated with salt (Heavy salted) or partially saturated to a salt content not less than 10 percent by weight of the salted fish which has been dried. The product shall be free from foreign matter, objectionable odour and flavour. The product may contain food additives permitted in Appendix C. The product shall conform to the microbiological requirement given in Appendix D. The products shall conform to the following requirements:

Sl. No.	Characteristics	Requirements
(1)	Moisture	Not more than 16.0 percent
(2)	Sodium chloride	Not less than 10.0 percent and Not more than 15.0 percent
(3)	Ash insoluble in HCL on dry basis	Not more than 1.0 percent
(4)	Yeast and Mould Count	Absent in 25gm

A 35.08 Canned finfish means the product prepared from the flesh of fresh finfish of sound quality belonging to any one species or mixture of species within the same genus having similar sensory properties. The product shall be free from head, tail and viscera. The product may be packed in any suitable packing medium. The packaging medium and other ingredients used shall be of food grade quality. The products shall conform to the following requirements:

Sl. No.	Characteristics	Requirements
(1)	Histamine Content	Not more than 20 mg/ 100 gm
(2)	Total Volatile Base (Nitrogen)	Not more than 30 mg/ 100 gm

A 35.09 Canned Shrimp means the product prepared from fresh shrimp of sound quality from any combination of species of families Penaeidae, Pandalide, Crangonidae and Palaemonidae from which heads, shell and antenna have been removed. The product may be in the form of peeled shrimps which have been headed and peeled without removal of the dorsal tract or cleaned and deveined shrimps in which the back is cut open after peeling and dorsal track has been removed upto the last segment next to the tail or broken shrimps consisting of pieces of peeled shrimp of less than four segments with or without

the vein removed. The packing medium and other ingredients shall be of food grade quality. The products shall conform to the following requirements:

Sl. No.	Characteristics	Requirements
(1)	Total Volatile Base (Nitrogen)	Not more than 30 mg/ 100 gm
(2)	Acidity in brine expressed as Citric Acid	Not more than 0.2 percent

A 35.10 Canned sardines or sardine type products means the product prepared from fresh or frozen fish belonging to Sardinia pilchardus, Sardinia milanostictusl neopilchardusl ocellatus/ sag ax/ caeruleus, Sardinia aurita/ brasiliensisl maderensisl longicepsl gibbosa celupea harengus, Sprattus sprattus, Hypertophus vittatus, Nematolosaviaminghi, Etrumeus teses, Ethmedium maculatun, Engranulis anchoita/ mordax/ ringens and opisthonema oglinum.

The product shall be free from head and gills,. It may be free from scales and/ or tail. The fish may be eviscerated. If eviscerated it shall be practically free from visceral parts other than roe milt or kidney. If ungutted it shall be practically free from undigested feed or used feed. The product shall be packed in any suitable medium. The packing medium and all other ingredients shall be of food grade quality. The products shall also conform to the following requirements:

Sl. No.	Characteristics	Requirements
(1)	Histamine Content	Not more than 20 mg/ 100 gm
(2)	Total Volatile Base (Nitrogen)	Not more than 30 mg/ 100 gm

A 35.11 Canned salmon means the product prepared from fresh fish of sound quality belonging to any of the species of Salmosalar or Oncorhynctus nerka/ kisutchl tschawytscha/ gorboscha/ ketax and masou species. The product shall be tree from head, viscera, fins and tails. The product shall be packed in any suitable medium. The packing medium and all other ingredients shall be of food grade quality No food additive is allowed in this product. The product shall conform to the following requirement:

Sl. No.	Characteristics	Requirements
(1)	Total Volatile Base (Nitrogen)	Not more than 30 mg/ 100 gm

A 35.12 Canned crab meat means the product prepared fro live crabs of sound quality from any of the edible species of the suborder Branchyura or the order Decapoda and all species of the family Lithodiadae. The product shall be prepared singly or in combination from the leg, claw, body and shoulder meat from which the shell has been removed. The product shall be packed in any suitable medium. The packing medium and all other ingredients shall be of food grade quality. The products shall conform to the following requirements:

Sl. No.	Characteristics	Requirements
(1)	Total Volatile Base (Nitrogen)	Not more than 30 mg/ 100 gm
(2)	Acidity in brine expressed as Citric Acid	Not less than 0.06 percent and Not more than 0.2 percent

A 35.13 Canned Tuna and Bonito means the product prepared from fresh fish of sound quality belonging to Thunnus alalunga/ albacaresl atlanticusl obesusl maccoyiil thynnusl tongoe, Euthynnus affinisl alleteratusl Jinlatus/ Sarda chilentis/ orienlalisl Sarda and Katsuwonus pelamis (syn Euthynnus pelamis) species. The product may be in the form of segments with or without skin, chunks, flakes or grated/ shredded particles. The product shall be packed in any suitable medium. The packing medium and all other ingredients shall be of food grade quality. The products shall conform to the following requirements:

Sl. No.	Characteristics	Requirements
(1)	Histamine Content	Not more than 20 mg/ 100 gm
(2)	Total Volatile Base (Nitrogen)	Not more than 30 mg/ 100 gm

Note II: All the product listed under items A35.08, A35.09, A35.10, A35.11, A35.12 and A35.13 shall be packed in hermetically sealed clean and sound containers and subjected to adequate heat treatment followed by rapid cooling to ensure commercial sterility. The container shall be free from rust and mechanical defects. The container shall not show any change on incubation at 37^0C for 7 days. The final product shall be free from foreign matter, objectionable odour, or flavour. The products may contain food additives permitted in Appendix C except products listed under A35.11. The product shall conform to the microbiological requirement given in Appendix D".

3. In the said rules, in Appendix C, after Table 4, the following table shall be inserted, namely:

"Table 5
List of Food Additives for use in Fish and Fish Products

	Name of the additive	Frozen Shrimps	Frozen Lobsters	Salted Fish	Frozen finfish	Canned finfish	Canned Shrimps	Canned Sardines	Canned Tuna and Bonito	Canned Crab meat	Frozen Fish Fillets
1	2	3	4	5	6	7	8	9	10	11	12
A.	**Antioxidants**										
1.	Ascorbic acid	GMP	-	-	-	-	-	-	-	-	-
2.	Sodium and Potassium Ascorbate singly or in combination expressed as Ascorbic acid	-	1gm/ Kg maximum	-	1gm/ Kg maximum	-	-	-	-	-	1gm/ Kg maximum
B.	**Acidifying agents**										
1.	Acetic acid	-	-	-	-	GMP	-	GMP	GMP	-	-
2.	Citric acid	GMP	-	-	-	GMP	GMP	GMP	GMP	GMP	1gm/ Kg maximum in minced fish flesh only
3.	Lactic acid	-	-	-	-	GMP	-	GMP	GMP	-	-
C.	**Moisture Retention Agents singly or in combination including natural phosphate expressed as P205**										
1.	Sodium polyphosphate expressed as P205	10gms/ Kg maximum	10gms/ Kg maximum	-	-	-	-	-	10gms/ Kg maximum expressed as P205 (including natural phosphate)	10gms/ Kg maximum expressed as P205 (including natural phosphate)	10gms/ Kg maximum expressed as P205 (including natural phosphate)
2.	Potassium polyphosphate expressed as P205			-	-	-	-	-			
3.	Calcium polyphosphate expressed as P205			-	-	-	-	-			
4.	Orthophosphoric Acid	-	-	-	-	-	850mg/ Kg maximum	-	-	-	-
D.	**Preservatives**										
1.	Potassium bisulphite expressed as Sulphur Dioxide	100mg/ Kg maximum raw edible /30 mg/ Kg maximum cooked product.	100mg/Kg maximum raw edible /30mg/ Kg maximum cooked	-	-	-	-	-	-	-	-
2.	Potassium Sulphite expressed as sulphur di-oxide			-	-	-	-	-	-	-	-

1	2	3	4	5	6	7	8	9	10	11	12
3.	Sodium metabisulphite expresses as sulphur dioxide	Singly or in combination expressed as SO2	product, Singly or in combination cooked product	-	-	-	-	-	-	-	-
4.	Sodium sulphite expressed as sulphur sulphur dioxide			-	-	-	-	-	-	-	-
5.	Sodium Sorbate expressed as sorbic acid	-	-	200mg/ kg maximum, singly or in combination expressed as sorbic acid	-	-	-	-	-	-	-
6.	Calcium sorbate expressed as sorbic acid	-	-		-	-	-	-	-	-	-
7.	Potassim Sorbate expressed as sorbic acid	-	-		-	-	-	-	-	-	-
8.	Sorbic Acid	-	-		-	-	-	-	-	-	-
E.	**Colours**										
1.	Ponceau 4 R	30mg/Kg maximum cooked mass	-	-	-	-	-	-	-	-	-
2.	Sunset Yellow	-	-	-	-	-	30mg/ Kg maximum singly or in combination	-	-	-	-
3.	Tartarazine	-	-	-	-	-		-	-	-	-
F.	**Thickening agents**										
1.	Pectin	-	-	-	-	2.5gm/ Kg maximum	-	-	2.5gm/Kg maximum	-	-
2.	Trangacanth Gum	-	-	-	-	-	-	20gm/kg maximum singly or in combination in packing medium only	20gm/ kg maximum singly or in combination in packing medium only	-	-
3.	Xanthan Gum	-	-	-	-	-	-			-	-
4.	Sodium/ Potassium/ Calcium Alginate	-	-	-	-	-	-			-	5mg/ kg maximum as Sodium Alginate
5.	Carboxy Methyl Cellulose	-	-	-	-	2.5gm/ Kg maximum	-	-	-	-	-

1	2	3	4	5	6	7	8	9	10	11	12
G.	**Modified Starches**										
1.	Acid Treated Starch	-	-	-	-	60gm/ Kg maximum in singly or in combination in packing medium only	-	60gm/ Kg maximum singly or in combination in packing medium only	60gm/Kg maximum singly or in combination in packing medium only	-	-
2.	Alkali treated Starch	-	-	-	-		-			-	-
3.	Balanced starched	-	-	-	-					-	-
4.	Distarch adipate acceylated	-	-	-	-		-			-	-
5.	Distarch glycerol	-	-	-	-		-			-	-
6.	Distarch glycerol, acetylated	-	-	-	-		-			-	-
7.	Distarch glycerol, hydroxyproply	-	-	-	-		-			-	-
8.	Distarch phosphate	-	-	-	-		-			-	-
9.	Distarch phosphate, acetylated	-	-	-	-		-			-	-
10.	Distarch phosphate, hydroxypropyl										
11.	Monostarch phosphate										
12.	Oxidezed starch										
13.	Starch acetate										
14.	Starch, hydroxypropyl										
H.	**Natural Flavours**										
1.	Natural Flavours and Natural Flavouring substances	-	-	-	-	GMP	-	GMP	GMP	-	-
I.	**Flavour Enhancers**										
1.	Monosodium Glutamate	-	-	-	-	-	-	-	-	500mg/ Kg maximum	-
J.	**Seqestering Agents**										
1.	Calcium Disodium EDTA	-	-	-	-	-	250mg/Kg maximum	-	-	250mg/ Kg maximum	-

4. In the said Rules, after Appendix C, the following Appendix shall be inserted, namely:

"Appendix D (See Rule 5)

Table-1

Microbiological requirements for Sea Foods

Sl. No.	Name of the Product	Total Plate Count	E. coli	Staphylococcus aureus	Salmonella & Shigella	Vibro cholerae	Vibro parahaemolyticus	Clostridium perfringens
1	2	3	4	5	6	7	8	9
1.	Frozen shrimps or Prawns							
	Raw	Not more than five lakhs/ gm	Not more than 20/gm.	Not more than 100/gm.	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
	Cooked	Not more than one lakh/ gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-

1	2	3	4	5	6	7	8	9
2.	Frozen Lobsters							
	Raw	Not more than five lakhs/ gm	Not more than 20/gm.	Not more than 100/gm.	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
	Cooked	Not more than one lakh/ gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
3.	Frozen squid	Not more than five lakhs/ gm	Not more than 20/gm.	Not more than 100/gm.	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
4.	Frozen finfish	Not more than five lakhs/ gm	Not more than 20/gm.	Not more than 100/gm.	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
5.	Frozen fish fillets or minced fish flesh or mixtures thereof	Not more than five lakhs/ gm	Not more than 20/gm.	Not more than 100/gm.	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
6.	Dried shark fins	Not more than five lakhs/ gm	Not more than 20/gm.	Not more than 100/gm.	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
7.	Salted fish/ dried salted fish	Not more than five lakhs/ gm	Not more than 20/gm.	Not more than 100/gm.	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
8.	Canned finfish	Nil	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm
9.	Canned shrimp	Nil	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
10.	Canned sardines or sardine type products	Nil	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
11.	Canned salmon	Nil	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
12.	Canned crab meat	Nil	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-
13.	Canned Tuna and Bonito	Nil	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	Absent in 25 gm	-

[F.No. P.15014/10/2002-PH (Food)]
RITA TEAOTIA. Jt. Secy.

Note: The Prevention of Food Adulteration Rules 1955 were published in Part II, Section 3 of Gazette of India vide S.R.O. 2106, dated the 12th September, 1955 and were last amended vide G.S.R......................dated.........................

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,
ರಿಚಾರ್ಡ್ ಲೋಬೋ
ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ
ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,
ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಪಿ.ಆರ್. 118